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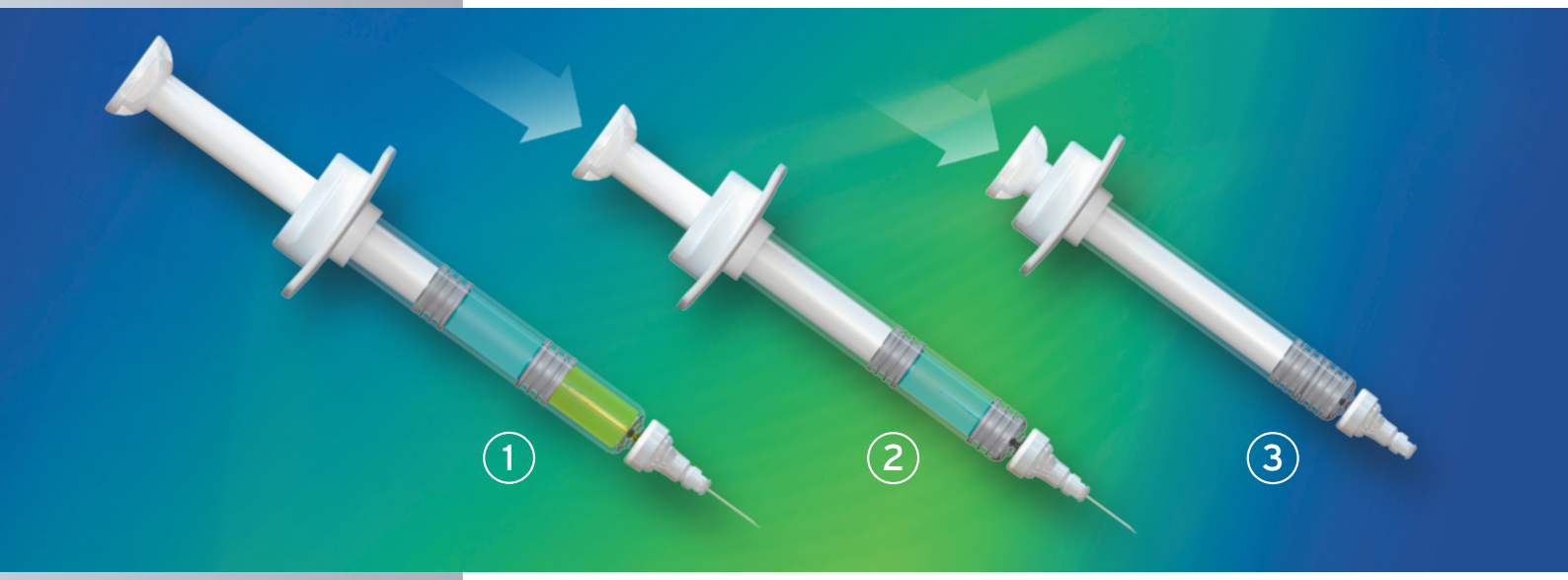


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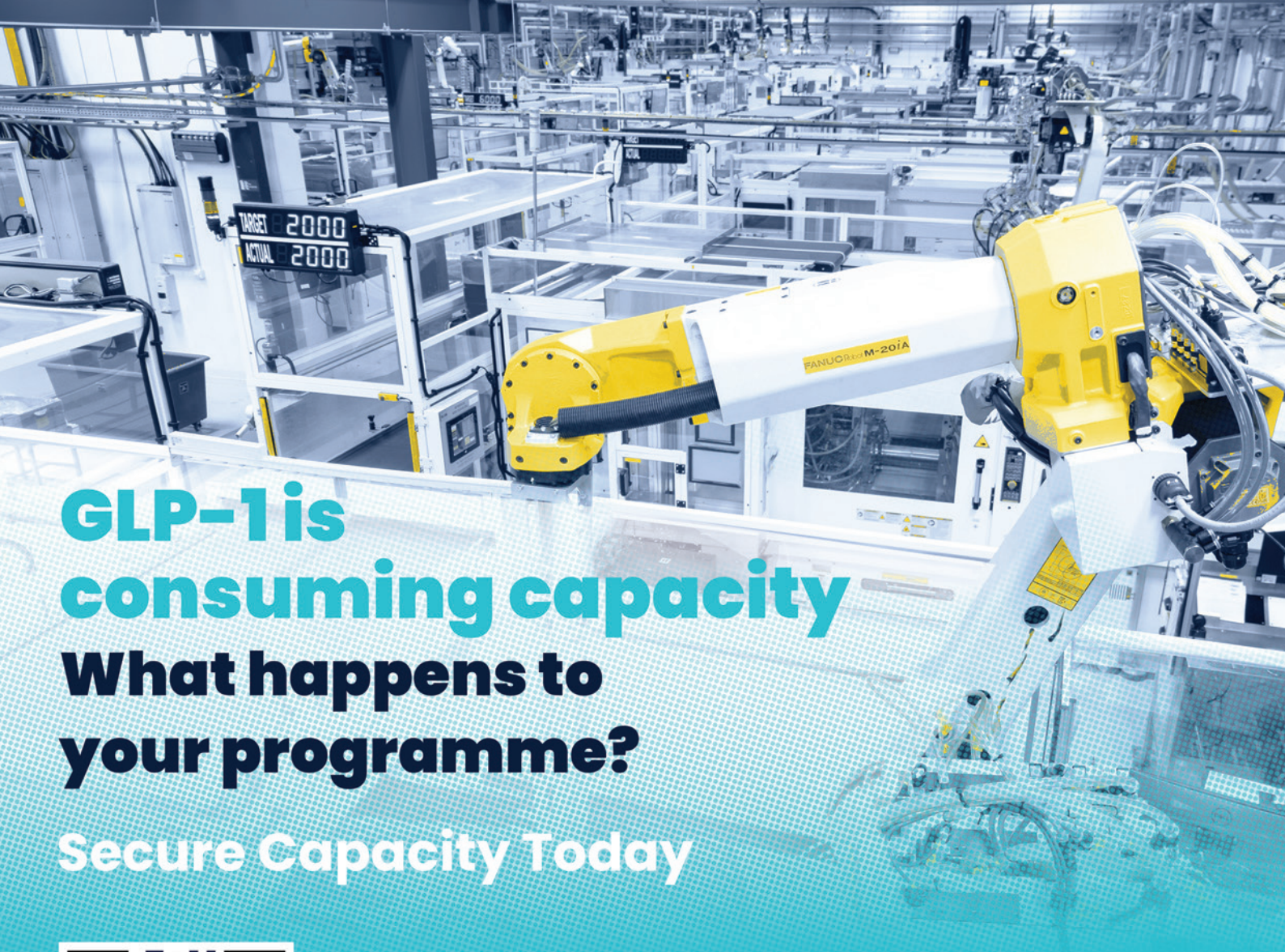
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PREFILLED SYRINGES & INJECTION DEVICES

ONdrugDelivery Issue N° 191, October 5th, 2026

This edition is one in the ONdrugDelivery series of publications. Each issue focuses on a specific topic within the field of drug delivery, and is supported by industry leaders in that field.

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Autumn of Injection Part III:
Autoinjectors & Prefilled Syringes

In this final instalment of ONdrugDelivery's 2026 Autumn of Injection, we are pleased to present a cornucopia of injection devices across a record-breaking issue. That this is the biggest issue of ONdrugDelivery ever represents further evidence of how injectables have captured the zeitgeist in the pharmaceutical world, as the drug delivery industry innovates to meet the needs of the challenging and sensitive biologics working their way through today's drug development pipelines. This core theme is examined extensively in these pages, with contributors coming at it from a variety of angles and perspectives.

Kicking the issue off, our Outstanding Sponsor, **Ypsomed**, discusses how the platform approach to device development enables device designers to build up a corpus of knowledge that can be taken forwards to inform future projects (Page 10). Alongside them, our first Key Sponsor, **SHL Medical**, introduces Magnitude – a modern rebrand of the company's highly successful Maggie cartridge-based autoinjector (Page 18). Our second Key Sponsor, **Ensera**, digs deeper into platform devices, putting the gap between selecting a platform and having a combination product ready for market under the microscope (Page 24).

We continue with a retrospective from **Sanner** and **Takeda**, looking back at novel devices that never quite made it (Page 30), and **Team Consulting** takes a closer look at the challenges involved with engineering the end-of-dose "click" for autoinjectors (Page 40). Following them, **Crux** and **Takeda** share insights into potential future paths for platform devices discussed at the SAE's PFS & Injectable Drug Devices East Coast Conference in Boston earlier this year (Page 46). Then, **Aptar Pharma** considers the value of USP <382> in early decision making (Page 51), and **BD** shares details of its global sterile manufacturing strategy (Page 56).

Naturally, the focus of the issue majors on devices. We feature exclusive interviews with Michael Earl and Steven Kaufman of **Eco-Inject** (Page 62) and Patrick Anquetil of **Portal Instruments** (Page 125), as well as a range of articles discussing diverse device solutions. The device-focused articles in this issue include a look at the pre-verified combinations of the Aidaptus® autoinjector platform with **Stevanato Group**'s Nexa® and Alba® syringes (Page 66); the first-of-its-kind combined prefillable syringe and passive safety system developed together by **SCHOTT Pharma** and **Nemera** (Page 81); **West**'s Synchrony™ S1 prefillable syringe system (Page 88); **Gerresheimer**'s Gx Inbeneo® 3 mL autoinjector and 5 mL concept (Page 106); **Nipro**'s ENOVIA™ biopharmaceutical-grade prefillable syringes (Page 112); an investigation into the effects of freeze-thaw on **Unither**'s Euroject® system (Page 120); **SMC Ltd**'s Bios platform (Page 145); and **GAPLAST**'s implantable delivery system (Page 160).

A common thread throughout the Autumn of Injection trilogy has been that there is much more to the drug delivery industry than just devices, with an ecosystem of companies working together to bring the right equipment and expertise together to see that combination products make it successfully into the hands of patients. Included in this cohort are a showcase on technology transfer from **Lifecore Injectables** CDMO (Page 72); a consideration of the implications of silicone-free prefillable syringes for functional testing from **Instron** (Page 94); a discussion of springs and stamped metal parts from **RPK Medical** (Page 100); a showcase on fill-finish capabilities from **Grand River Aseptic Manufacturing** (Page 118); an examination of integrated, turnkey assembly solutions from **DROFEN MACHINERY** (Page 136); an in-depth look into cannula technology from **Jecture** (Page 140); a look at evolving testing standards from **ZwickRoell** (Page 152); and an explanation of the levels of automation and return-on-investment factors from **BBS Automation** (Page 165).

Rounding out the issue, we feature a trio of reviews into some of the science behind the evolution of modern injectable devices. First, **Sanner Group** investigates the physics of using suspension-based therapeutics in injection devices (Page 74). Second, **Novo Nordisk** and **Crux** review a recently published study into quantifying the forces that female users exert when using a shield-activated autoinjector (Page 130). And third, concluding the issue, **BD** present recent work into establishing a rigorous testing programme for ensuring container closure integrity for prefillable syringes under deep-freeze conditions (Page 172).

Additionally, **ONdrugDelivery** will be present at **CPHI Milan!** Please come and visit us in the Media Hub in Hall 16 (Stand 16F08).

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FOR THE RECORD: HOW PAST EXPERIENCE ENABLES FUTURE SUCCESS

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Dr Jakob Lange and **Shawn James** of **Ypsomed** discuss the value of the experience hidden behind metrics such as completed projects and commercialised devices – the wealth of accumulated process knowledge that enables a company to bring hard-learned lessons forwards to benefit each new development programme and evolve its product portfolio to meet the needs of an evolving sector.

Every pharmaceutical company evaluating the track record of a drug delivery partner starts with roughly the same checklist – years in business, products launched, devices delivered, manufacturing capacity, number of customers and partnerships, regulatory approvals. These figures are real, and they matter, because they show that a company has repeatedly navigated the technical, regulatory and industrial demands of bringing a combination product to market. They demonstrate that a company's technologies have progressed beyond concepts and prototypes, its manufacturing has progressed beyond pilot production and its regulatory strategies have been tested under real commercial conditions. They provide proof.

What they cannot show is what the company has actually learned in the process, and that is the harder, more useful question for any leadership team choosing a long-term partner. Every development programme builds on and adds to an existing body of knowledge: engineering insights, human factors evidence, regulatory precedent and manufacturing lessons that only become visible once a product is marketed at commercial scale. When those lessons are captured and disseminated rather than left tied to a single project, experience stops simply being a record of the past and becomes a resource that the next customer can inherit before their development programme has even begun.

Ypsomed's four decades in the self-injection industry are a useful test of that

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Figure 1: Ypsomed has been innovating in self-injection devices for over 40 years.

idea. More than 80 commercial combination products is a meaningful figure in its own right, but the more telling detail is what sits behind it – thousands of engineering decisions, usability findings, manufacturing refinements and regulatory conversations that continue to shape the company's platforms in development today. Viewed this way, experience is less a summary of what has already been delivered and more a foundation for what can be built next.

KNOWLEDGE UNLOCKED: HOW A PLATFORM APPROACH OPENS DOORS

Ypsomed's earliest devices were built to solve very different problems. OptiPen, launched in 1985, helped move insulin delivery beyond syringes and vials, while KabiPen followed in 1989 with a dual-chamber cartridge designed for lyophilised growth hormone. OptiSet, introduced in 1999, brought preset dosing to reduce dosing errors and the Gonal-f pen extended the company's device experience into fertility treatment for the first time. Each programme asked something different of the organisation in terms of therapeutic, technical and usability requirements, and together they built an understanding of how to design, validate and industrialise self-injection systems that no single project could have produced alone.

The more significant shift came in 2006, when Ypsomed moved from bespoke device development towards modular platforms. Rather than starting each new project from a blank page, proven architectures became the technical foundation for future development programmes while remaining adaptable to different drugs, containers, patient populations and commercialisation strategies. Shorter development timelines were one outcome of that shift, but the more consequential one was structural; every subsequent programme now contributes back to the platform itself, allowing engineering knowledge to accumulate across programmes rather than remaining locked inside any single product (Figure 1). This raises the question at the centre of this article – if experience is meant to transfer from one programme to the next, how much of it actually carries forwards?

> "EACH PROGRAMME ASKED SOMETHING DIFFERENT OF THE ORGANISATION IN TERMS OF THERAPEUTIC, TECHNICAL AND USABILITY REQUIREMENTS, AND TOGETHER THEY BUILT AN UNDERSTANDING OF HOW TO DESIGN, VALIDATE AND INDUSTRIALISE SELF-INJECTION SYSTEMS THAT NO SINGLE PROJECT COULD HAVE PRODUCED ALONE."

COMPOUND INTEREST: HOW EXPERIENCE PAYS OFF

The answer is that not everything carries forwards. Some lessons remain specific to a particular molecule, container or patient population, while others prove useful across many development programmes; distinguishing between the two is a substantial part of the engineering challenge itself.

The primary container illustrates this well. An autoinjector performs as an integrated system, and its behaviour depends on the interaction between the device and the container it surrounds – break-loose and glide forces, siliconisation, dimensional tolerances and needle-shield removal all influence injection performance, and small variations can affect injection time, drive-system behaviour and the assembly process. Each combination product still requires its own technical assessment and historical experience does not substitute for that work. What it does provide is established test methods, historical performance data and a clearer sense of where risk is most likely to emerge.

Human factors evidence accumulates along similar lines. Self-injection devices are used by people with varying levels of dexterity, confidence and experience, typically without professional supervision, and any single study can only answer a defined question for a defined population. When considered together, however, a large body of studies begins to reveal patterns that are difficult to observe within one development programme alone: where users hesitate, which interface choices consistently reduce errors and which assumptions are worth challenging

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"THE TWO-STEP, BUTTON-FREE USER INTERFACE OF YPSOMATE REFLECTS YEARS OF OBSERVING HOW PEOPLE APPROACH SELF-INJECTION OUTSIDE A CLINICAL SETTING."

before the next study begins. The two-step, button-free user interface of YpsoMate reflects years of observing how people approach self-injection outside of a clinical setting. In 2025/26 alone, Ypsomed conducted more than 25 human factors studies involving over 1,200 participants, adding to an evidence base that now spans multiple therapies, patient populations and levels of user experience.

Regulatory understanding accumulates in a similar way, and its reach occasionally extends well beyond a single programme. Questions raised during previous reviews, approaches regulators have accepted and evidence generated across many submissions gradually build a broader picture of regulatory expectations. The EMA's qualification of the molecule-independent device bridging approach, supported by evidence generated on the YpsoMate and YpsoMate 2.25 mL platforms, is a case in which platform-level evidence contributed to an entirely new regulatory methodology.

Manufacturing experience compounds in much the same way, since device design, assembly, tooling, process validation and quality control are closely connected, and knowledge gained industrialising one product directly informs the design, technology transfer and scale-up of the next.

Taken together, these different forms of experience produce something a launch count cannot capture on its own. Experience accumulated across a broad range of therapies and development programmes builds engineering judgment about where established knowledge applies, where genuine uncertainty remains and where further investigation is warranted before a decision is made (Figure 2).

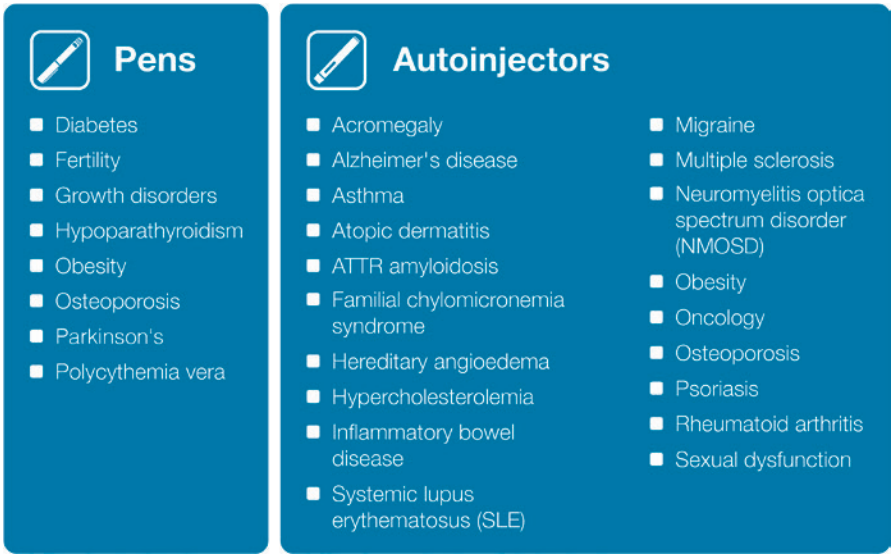


Figure 2: Platform experience spans a broad range of therapies, patient populations and treatment contexts.

FIT FOR PURPOSE: GETTING PLATFORMS INTO SHAPE

If accumulated experience could simply be copied from one development programme to the next, combination product development would be considerably more predictable than it actually is. Every programme introduces its own variables – formulation, viscosity, injection volume, primary container, intended users, injection frequency, regulatory strategy and commercial objective – and a platform well suited to one therapy may be the wrong starting point for another. Experience does not eliminate those differences. What it does provide is the context needed to identify and evaluate variables more quickly.

Platform-based development does not require a trade-off between standardisation and optimisation. In reality, the relationship tends to run the other way – a well-understood platform provides a stable technical foundation precisely because it allows a development team to concentrate on what is genuinely specific to a development programme rather than revisiting engineering questions that earlier programmes have already answered. As pharmaceutical pipelines diversify, the value lies in combining accumulated experience with a broad portfolio of configurable platforms, allowing the most appropriate starting point to be selected and configured to match the specific needs of each new programme.

Ypsomed's own platform portfolio has evolved along the same lines as the questions it has been asked to answer. The challenges facing self-injection in 2026 are not the ones the company was addressing when its first pens reached patients. At the same time, expectations have extended well beyond device performance alone – sustainability is influencing material selection and product architecture, digital technologies are supporting therapy management and increasingly successful self-administered therapies are placing new demands on manufacturing capacity and global supply.

Recent platforms reflect that evolution directly. YpsoLoop applies established autoinjector usability to a platform designed for circularity, with automated disassembly and material recovery. YpsoFlow and YpsoDot extend the portfolio into emerging biologic and peptide therapies, incorporating bio-based materials and new architectures. CliniPilot and the Clear to Clinic offerings support customers from clinical development through commercialisation, while the SmartPilot family extends established injection platforms with connected capabilities. Each addresses a different therapeutic and commercial requirement, yet all of them draw on the same underlying engineering disciplines, usability principles and industrial experience, built across more than 80 commercialised combination products and applied differently in each case (Figure 3).

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REPEAT PERFORMANCE: PRODUCTION IN THE SPOTLIGHT

Engineering knowledge has limited value if it cannot be translated into reliable commercial supply. Every combination product eventually reaches the point where laboratory testing, usability studies and regulatory submissions give way to manufacturing reality: processes must be validated, supply chains must remain robust and production capacity must grow alongside demand without compromising consistency. This is where challenges emerge that are often invisible at a smaller scale, and it is where an organisation's manufacturing experience is genuinely built.

That experience also shapes investment decisions – since capacity cannot be built solely for today's products; it must anticipate future demand and support customers across the full commercial lifecycle of successful therapies. Ypsomed's recent investments reflect that long-term view. An expansion at Ypsomed's Schwerin (Germany) site, inaugurated in 2024, added capacity for 100 million pens and autoinjectors annually. A further expansion currently underway represents an investment of more than CHF500 million (£456 million) and is expected to add approximately 400–500 million devices of annual capacity. In China, Ypsomed opened its Changzhou facility in 2025, with capacity for up to 100 million devices annually for the Chinese market. Together, these investments support the company's commitment to an annual production capacity of one billion self-injection devices by 2030 (Figure 4).

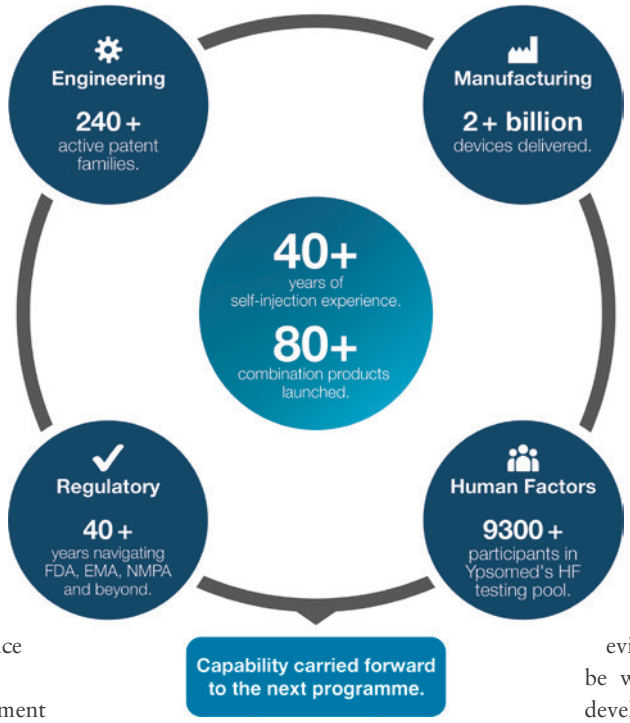


Figure 3: How experience accumulates and compounds across Ypsomed.

> "THAT EXPERIENCE ALSO SHAPES INVESTMENT DECISIONS – SINCE CAPACITY CANNOT BE BUILT SOLELY FOR TODAY'S PRODUCTS; IT MUST ANTICIPATE FUTURE DEMAND AND SUPPORT CUSTOMERS ACROSS THE FULL COMMERCIAL LIFECYCLE OF SUCCESSFUL THERAPIES."

That continuity matters more than it might initially seem, because a partner selected during clinical development may remain responsible for commercial supply for a decade or longer. In that context, reliability is measured not simply by what has already been delivered, but by the ability to apply accumulated experience consistently across development, industrialisation and long-term supply. Engineering expertise, manufacturing capability and long-term capacity are not separate considerations in that context; in practice they are a single decision made early and relied upon for years.

Ultimately, the strongest evidence of a partnership's value may be what customers choose to do once a development programme is complete, or even before a specific programme has finished. Choosing a partner for the first time is a matter of due diligence and technical evaluation. Selecting the same partner again reflects something else: direct experience of how the relationship performed across development, regulatory review, technology transfer and commercial supply. Repeat business partnerships, seen in that light, are not simply a commercial metric but a demonstration of confidence built through delivery; two in three of Ypsomed's customers are engaged in multiple projects.



Figure 4: Ypsomed's global manufacturing network – spanning Switzerland, Germany, China and the United States – is scaling towards 1 billion devices in annual capacity.

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FOR FUTURE REFERENCE: PUTTING THE PAST TO WORK

Metrics such as years in business, commercial launches and manufacturing capacity remain meaningful indicators of experience. They provide evidence of what has already been achieved. Their greater value, however, lies in the accumulated experience they represent: engineering judgment, human factors evidence, regulatory understanding and manufacturing knowledge. These are the assets that allow each new development programme to begin from a stronger position than the last, applying proven knowledge where it fits, identifying uncertainty earlier where it does not and supporting better decisions throughout development.

For more than four decades, Ypsomed has continued to accumulate and apply that experience, bringing it to each new programme while continuing to develop platforms and capabilities for changing therapeutic needs, connected healthcare and more sustainable product design. Every commercial programme adds a further layer of understanding; every new platform applies that understanding differently.

A track record is often treated as a record of the past. Its real value lies in what it makes possible in the future. That is the foundation Ypsomed is building from, and what makes it a partner that is chosen for the first programme – and trusted for the next.



Dr Jakob Lange

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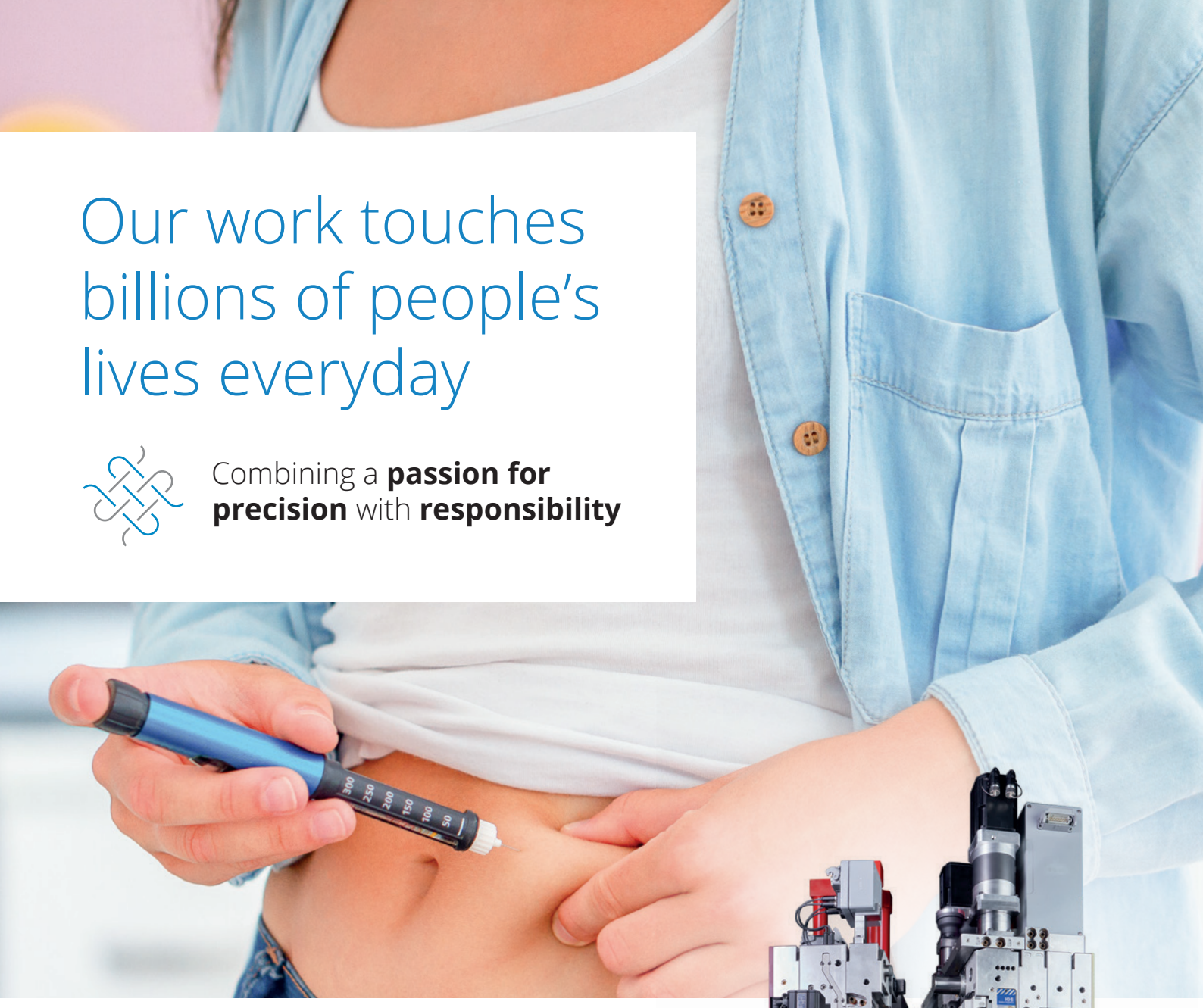
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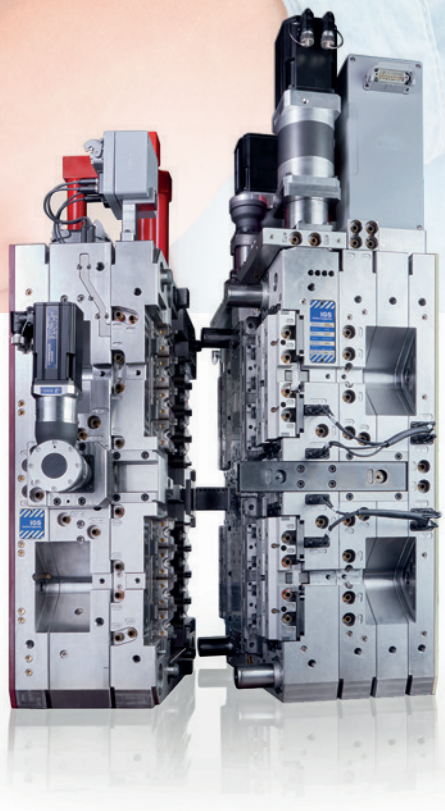
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Interview:
SHL Medical: When More Matters – Advancing Large-Volume Drug Delivery With Magnitude

In this interview, **Vince Masciopinto**, Customer Solutions Director of **SHL Medical**, discusses the strategic evolution of the company's Maggie platform into Magnitude while discussing large-volume delivery and considering the technical breakthroughs, market shifts and user insights that define its growth.

Q **Can you introduce SHL Medical's new offering, Magnitude?**

A Well, it isn't really new. Magnitude is an evolution of the Maggie Platform to reflect what we have learned over the past few years. We have a couple of new capabilities that we are really excited about, and we are changing the name of the platform from Maggie to Magnitude.

Q **What exactly have you learned and what are these new capabilities?**

A There are two big enhancements – one that improves usability and one that expands the platform's performance window. Both changes are exclusive to the front sub-assembly. The rear sub-assembly, which contains the injection spring, continuous click feature, activation mechanism and vast majority of the components, remains completely unchanged.

The cap has been redesigned to make the device more intuitive and easier to use, and the cannula has been modified to provide a nearly 50% improvement in injection time. These enhancements have been informed by our experiences with customers and users.

"THE NAME MAGNITUDE IS MEANT TO EVOKE THE IDEA OF SOMETHING BIG OR LARGE, WHICH IS APPROPRIATE FOR OUR LARGE-VOLUME AUTOINJECTOR."

Q **Why change the name to Magnitude?**

A SHL has transitioned to a new naming convention that is more descriptive of the product itself, rather than using the names of people. You will have seen that reflected in our recent product launches of Quanta and Reunite in the last year or so. Following the successful introduction of Reunite, we're now rebranding Maggie to Magnitude, as an expansion of our portfolio of cartridge-based autoinjectors featuring our Needle Isolation Technology, NIT for short (Figure 1).

You'll notice that both devices include "NIT" within their names because we want the connection to this user-centric technology to be immediately clear. Additionally, the name Magnitude is meant to evoke the idea of something big or large, which is appropriate for our large-volume autoinjector. This is further emphasised in the tagline "When more matters".



Vince Masciopinto

Customer Solutions Director

E: vincent.masciopinto@shl-medical.com

Vince Masciopinto is currently a Customer Solutions Director at SHL Medical, where he is responsible for supporting pharma and biotech customers in the adoption of customised, complex and bespoke solutions. Mr Masciopinto works closely with business development, product management and other teams to guide customers in selecting the right drug delivery solution. He has decades of experience in the healthcare industry, having previously worked at companies such as Eitan Medical and West Pharmaceutical Services.

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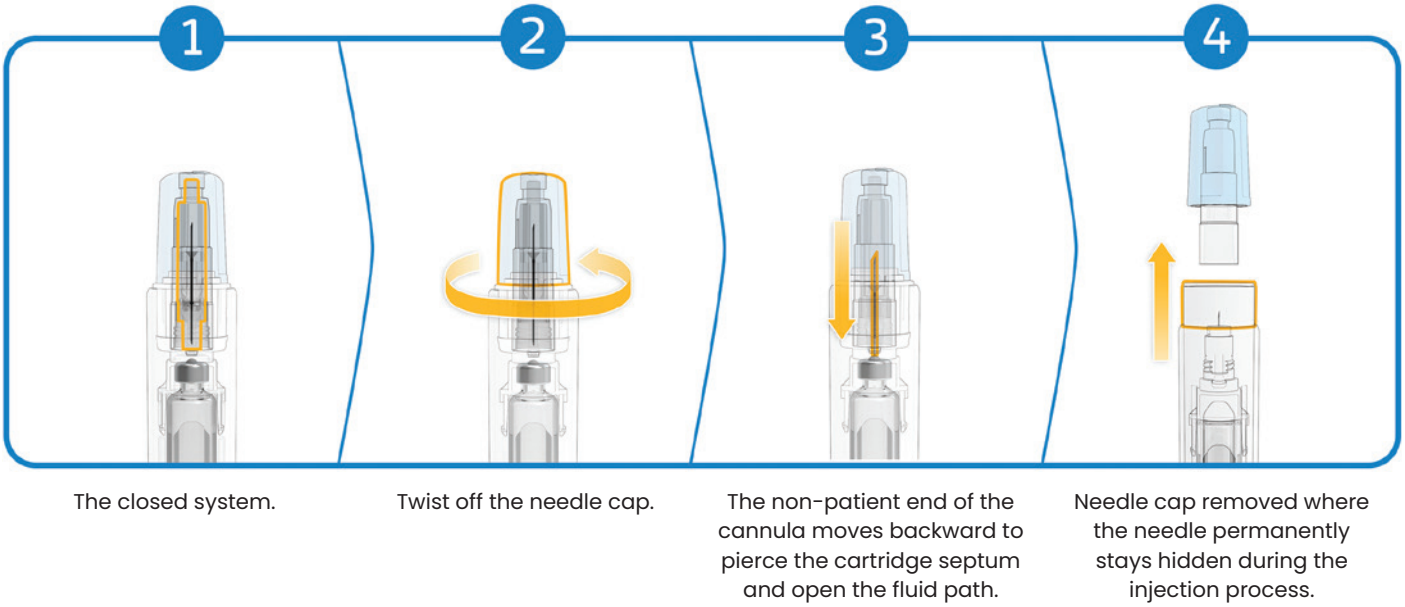


Figure 1: An overview of SHL Medical's NIT.

Q Can you go into more detail on Magnitude's enhanced performance?

A When we started development of a large-volume autoinjector, we knew it had to use a traditional compression spring as the "engine" of the device. Throughout the years, we have evaluated and implemented many different spring technologies in other delivery systems. While there are useful applications for those other spring types, a compression spring offers significant advantages: small overall size, excellent manufacturing scale, unit economics, sustainability and, most importantly, reliability. The downside is the force profile, which resulted in an autoinjector that was slightly underpowered.

The most obvious answer here would be to change to a stronger spring, but that would negate all the advantages of a compression spring; instead, we decided to think a little differently. In a cartridge-based autoinjector, the needle isn't staked to the container like a syringe, which allows us to do some things with needle geometry that aren't possible with a syringe. With NIT, we have been able to replace a single needle with two needles. This split-cannula approach allows us to independently optimise each needle and improve flow where it matters for throughput, without changing the needle geometry that enters the injection site. The result is a roughly 50% improvement in injection time for a 27G patient-end needle without making any other changes to the device itself (Figure 2).

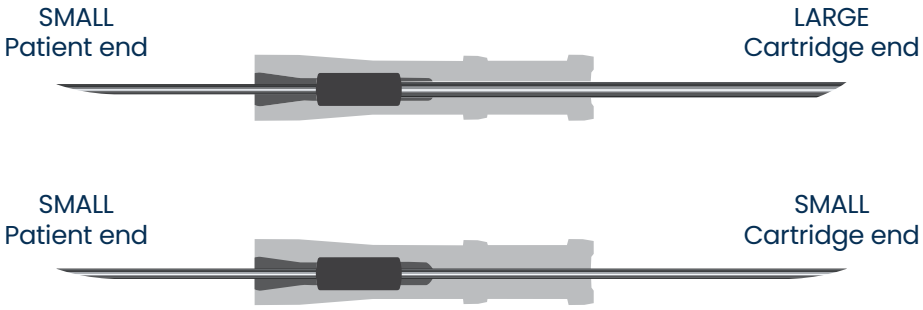


Figure 2: Image inset visualising SHL Medical's split-cannula approach.

Q Can you elaborate on the changes made to improve usability?

A The process of usability engineering is not a one-time event. We begin analysing risks early on in development and then continuously evaluate and improve our products throughout their lifecycle. Every time a user interacts with one of our products, it is an opportunity to learn something new. Magnitude is not the only product that includes the NIT technology. NIT was first commercialised back in 2018 and, since then, tens of millions of units have reached the hands of patients with great success. Still, we are constantly looking at opportunities for improvement, and we are in the process of rolling out one of those changes.

Specifically, the cap has been modified to make the intended twist-off motion clearer and to further enhance the intuitiveness of the overall user experience (Figure 3). Additionally, there are minor changes to help improve our manufacturing efficiencies

"EVERY TIME A USER INTERACTS WITH ONE OF OUR PRODUCTS, IT IS AN OPPORTUNITY TO LEARN SOMETHING NEW."

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as we look to bring in our European manufacturing site in Zug (Switzerland) to complement our North Charleston (SC, US) and Taoyuan (Taiwan) sites. Just like the change we discussed earlier, this change is also isolated to the front sub-assembly.

Q Other than these new changes, how else is Magnitude different from other device products targeting large-volume injections?

A First of all, let's define "large volume" to make sure we're talking about the same thing. To me, large-volume injections are above 2 mL and below 5 mL. At this point, injections of 2 mL and below are widely accepted, and there are several examples of autoinjectors at and below 2 mL made by many different manufacturers and device suppliers. Above 5 mL, delivery is less of an injection and more of an infusion. Within this space, there are essentially three options: split the dose across multiple smaller autoinjectors, use an on-body injector (OBI) or use a single large autoinjector.

The strategy of using multiple smaller injections to achieve a practical dose of larger volume has been successfully implemented in several cases. This also provides some flexibility to patients by offering the option of performing a single injection more frequently or multiple injections back-to-back less frequently. This strategy can also be used to support dose titration.

While smaller autoinjectors don't have the capacity to deliver above 2 mL, OBIs have the capability to deliver very large (10–50 mL) volumes and, in many instances, can perform infusions that are suited for very large volumes. They contain an adhesive patch that fixes the delivery system to the injection site, are often relatively large and contain complicated componentry. The additional capabilities often make OBIs cumbersome for the 2–5 mL volume range in the absence of an additional need, such as time-delayed delivery, controlled infusion or software control, and are much better suited for applications that require long or controlled infusions.

In-between smaller autoinjectors and OBIs are large autoinjectors that are purpose-built for 2–5 mL injections. Among them, Magnitude is unique because of the NIT technology. Being in a cartridge instead of a syringe has many benefits, including overall size; container performance in the form of improved drug stability, reduced silicone and better break loose and glide forces over shelf-life; and, because the fluid path is separate from the container, the fluid path can be optimised without impacting the container.



Figure 3: Cap design improvements for Magnitude.

"WITH NIT, THESE CHANGES CAN BE MADE INDEPENDENT OF THE CONTAINER AND DO NOT IMPACT ANY ONGOING STABILITY TESTING."

Q When you say "optimise" the fluid path, what exactly do you mean?

A There are a few ways to do it, depending on your goals. First and most obviously, is needle gauge. A larger needle can lower the injection time, which may be advantageous for usability and the overall patient experience. However, larger needle gauges may increase the risk of back leakage and insertion-related pain, whether perceived or physiological. Striking the right balance of these is often drug- or patient population-specific and is usually a decision that could benefit from real-world data.

With syringes, as the needle is staked to the container, so any changes to the needle gauge would necessitate a change to the container, which usually requires some additional stability work. With NIT, these changes can be made independent of the container and do not impact any ongoing stability testing.

Another characteristic with the potential for optimisation is the injection depth. Generally, most small volume (2 mL and below) autoinjectors have very similar injection depths, and the primary goal is to simply guarantee that the drug depot is in the subcutaneous layer across a variety of injection sites – typically the abdomen, thigh and back of arm. For larger injections, it is possible that deeper injections could offer some benefits, even if it would reduce the number of potential injection sites. As the depot grows larger, having it deeper in the subcutaneous layer could have positive impacts on pain, bleb size, formation and dissipation, back leakage and the injection experience for the user.

Q You mentioned that the device can deliver up to 5 mL – is an injection that large really possible?

A Yes, we've had customers approach us for a range of delivery volumes anywhere between 2 and 5 mL, all of

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which are achievable with the Magnitude platform. Each customer has their own needs, balancing delivery time, viscosity, needle gauge, dose frequency, etc. Recent internal SHL Medical studies have shown that different skin models can receive up to 5 mL with rates typical of an autoinjector. Many customers are working with us on a variety of dose volumes between 3 and 5 mL. We work with all of our customers to establish if Magnitude is the right solution for them.

Q **Size seems to be a key theme for Magnitude – why is it so important?**

A Keeping the device as small as possible has many advantages for our customers and patients. Users may already have anxiety about receiving an injection, and the size and weight of the device could exacerbate this and lead to usability errors. Thanks to the cartridge and compression spring, we have been able to keep Magnitude's size very similar to standard 2.25 mL autoinjectors while being able to deliver over twice the volume.

Beyond helping to reduce user anxiety around a very large and heavy device, Magnitude's compact footprint also offers economic and sustainability advantages. Using less raw material is only one part of the story; improved dunnage efficiency, especially in cold storage, can support better economics and a smaller environmental footprint across the supply chain – from warehousing to logistics and, ultimately, the patient's refrigerator.

"BEYOND HELPING TO REDUCE USER ANXIETY AROUND A VERY LARGE AND HEAVY DEVICE, MAGNITUDE'S COMPACT FOOTPRINT ALSO OFFERS ECONOMIC AND SUSTAINABILITY ADVANTAGES."

Q **Beyond device design, what does it take to make a large-volume autoinjector ready for customers to implement?**

A Before a device ever gets into a user's hands, it also must be manufactured and supplied. The drug delivery landscape includes many promising devices that fail to gain traction because they either cannot be manufactured or require new infrastructure that isn't feasible. When we set out to produce an autoinjector for large-volume subcutaneous injections, we knew that it would take more than just SHL Medical to make it happen and that it needed to be put in place before the first customer was ready. Through our Alliance Network, we have ensured that Magnitude is ready to implement today without significant investment from a partner. This includes options for the primary container, fill-finish processing, and final assembly, labelling and packaging tooling and processes.

Q **Where will people be able to meet you during the upcoming conference season?**

A I will be at the PDA Universe event in Palm Springs (CA, US) on October 6 and 7 presenting a Tech Talk on the subject, so feel free to stop by the talk or our booth and say hello or demo a sample. Otherwise, you can also find out more on our website.

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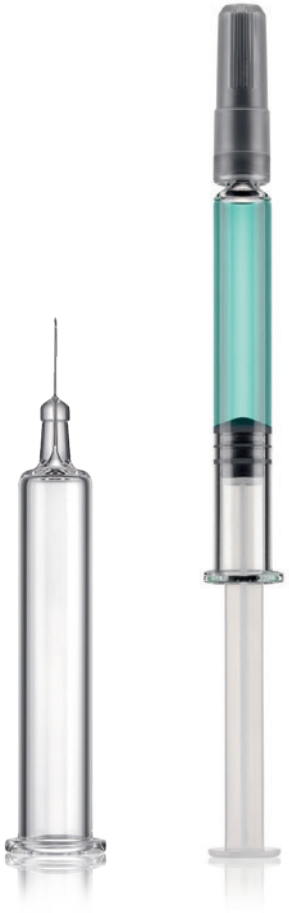
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THE PLATFORM ADOPTION GAP: WHY DEVICE SELECTION IS ONLY THE BEGINNING OF COMBINATION PRODUCT DEVELOPMENT

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Darren Hieber of **Ensera** investigates the often overlooked gap between selecting an injection device platform for a drug development programme and having a finalised combination product ready for commercialisation, digging into the various activities required to bridge the gap.

As pharmaceutical pipelines have shifted over the past decades, naturally, so too have the systems that support them. Of particular importance to the drug delivery sector has been the rise of platform devices as a means of simplifying development pathways and accelerating time to market. The appeal of platform products speaks for itself – an autoinjector platform, for example, offers a proven technology with a pre-established supply chain and, in many cases, will also have many of the device-related elements of a regulatory submission ready to use.

Compared with developing a bespoke delivery device in-house, platform devices offer lower risk and shorter development timelines – two factors that can be major differentiators for drug developers aiming to be the first to market. These benefits have significant appeal across the full spectrum of pharma companies, but they are especially relevant to those that lack their own device expertise. For example, emerging biotech companies with novel,

"THE PROLIFERATION OF PLATFORM PRODUCTS, WHILE A BOON TO THE INDUSTRY, HAS GIVEN RISE TO A COMMON MISCONCEPTION – THAT 'PLATFORM' EQUALS 'PLUG-AND-PLAY'."

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often challenging, biologic formulations can benefit enormously from buying in a proven platform pen injector, autoinjector or wearable device.

However, the proliferation of platform products, while a boon to the industry, has given rise to a common misconception – that "platform" equals "plug-and-play". In actual practice, while platform devices will accelerate and simplify the device development compared with designing a bespoke device from scratch, they do not obviate the need for development and device expertise entirely. A succinct way to describe this gap between misconception and reality is that while the device already exists, the combination product does not.

THE PLATFORM ADOPTION GAP

So, what does it take to turn a platform device into a market-ready combination product? Understanding how to bridge this gap and where responsibilities for the various aspects lie are critical to modern combination product development. While many device development companies and CDMOs can and do assist with turning a platform device into a marketed combination product, ultimate responsibility for design controls, risk management, verification, validation, regulatory submission and manufacturing readiness remains with the programme sponsor – it does not come packaged with the platform device.

In practice, what platform devices do for programme sponsors is change the process of device development, rather than eliminate it. Instead of extensive expertise necessary to design a drug delivery device from first principles, a platform device changes the process to one of demonstrating that a particular combination of drug, primary container, device architecture and user population all work together in concert to store and deliver the drug reliably and safely.

Ultimately, this process is guided by risk management. The initial hazard analysis and associated risk assessments define much of the development pathway, determining the evidence, testing and validation activities required for a specific combination product. This is a key reason why every platform device project remains unique, even when the underlying device is unchanged.

This work is anything but trivial. While platform devices undoubtedly offer a faster and lower-risk development pathway, it is easy to underestimate the amount of work and expertise required to bridge the gap between platform and combination product – especially for organisations embarking on a device development journey for the first time, or where the requirement is for low- to medium-batch volumes. For teams without their own device experts, working with outside expertise, such as a CDMO, can make the difference between a troubled and arduous development and bridging the gap to successful product launch and commercial scale-up in a smooth, controlled manner.

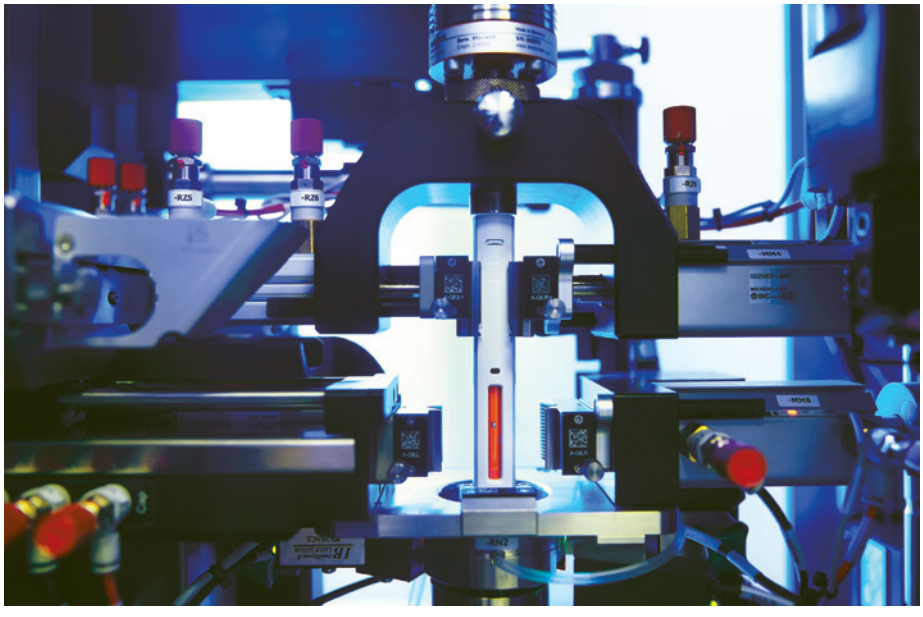


Figure 1: A platform autoinjector, undergoing functional testing on a ZwickRoell (Ulm, Germany) testing machine.

COMPATIBILITY IS NOT ASSUMED: VERIFYING THE DRUG-DEVICE SYSTEM

When carrying out initial research for a platform device, suppliers will typically offer prospective customers a defined operating range and compatibilities for their products. However, selecting the right platform device is not as simple as comparing the specifications given for a platform device with the anticipated requirements for the drug. Pharmaceutical development is rarely so simple. Every combination product represents a unique interaction between:

- The drug product
- The primary container
- The delivery device
- The intended use environment.

Every one of these factors has the potential to affect the suitability of a given platform device for a given drug programme. Consider just the drug product itself: the unique formulation characteristics of a drug all impact the requirements for the device. A key example of this is the viscosity, where device developers are currently competing to offer platform devices capable of delivering ever-higher viscosities to cater to the demands of increasingly challenging biologic formulations. Understanding the approach each of these competitors is taking and how it relates to the needs of both the drug formulation and the intended use environment is fundamental to choosing the right platform for the programme.

Some of the verification work that is typically required for a platform device includes (Figure 1):

- Lab-based performance testing
- Dose accuracy
- Injection time
- Container closure integrity
- Stability and efficacy studies
- In-use assessments.

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For a company expecting a platform device to be "plug and play" with their drug product, the amount of work required can be a rude awakening. Adopting a platform device does not obviate the need to demonstrate and validate the performance of the final drug-device combination product.

HUMAN FACTORS: PAST SUCCESS DOES NOT GUARANTEE FUTURE SUCCESS

Many platform device developers invest in applying human factors to develop and demonstrate this to some degree in their documentation to showcase that their devices are proven with patients. However, while it may be tempting to assume that the device developer's human factors testing is universally transferrable to any combination product programme, this is not the case – usability depends heavily on factors that can vary significantly from programme to programme.

The most important factor here is the intended user population – a device that performs well for one patient demographic may prove unsuitable in the hands of another. Different patient populations will have variations in expected dexterity, strength, cognitive ability, disease burden and therapy use environments, all of which can have a major impact on device suitability.

Is the therapy intended for use by a healthcare professional in a clinical environment? Is it meant for chronic at-home use by primarily elderly patients? Is it an emergency-use therapy that will need to be delivered in high-stress situations by a lay-person? The intended user population and use environment will determine what is required of not only the device but its packaging, labelling and instructions for use.

As such, even with mature platform devices, it is important for programme sponsors to conduct their own human factors testing with a prospective device.



Figure 2: A platform autoinjector, following semi-automatic assembly on a Mikron (Neuchâtel, Switzerland) MAIA assembly machine.

The device developer's testing will most likely have been with their own labelling and packaging, which can be noticeably different from the pharma company's own – and have an equally noticeable effect on usability.

Platform devices, by their nature, are intentionally standardised, so limitations revealed by a sponsor's own human factors testing can be difficult to modify. Therefore, it is important to be thorough at this stage, and for each development project to have its own usability engineering plan, to avoid unwelcome surprises further down the line. These activities should be integrated into the broader risk management process, ensuring that use-related risks identified throughout development are appropriately evaluated and mitigated.

THE HIDDEN WORK OF CLINICAL READINESS

Work does not stop with validation and human-factors readiness, however. Another aspect of combination product development that programme sponsors tend to underestimate is the amount of preparation required to reach the clinic. Before even clinical-scale manufacturing can begin, the following activities must be completed:

- Tooling procurement
- Tooling qualification
- Manufacturing documentation
- Process development
- Training
- Equipment configuration.

All of these activities require expertise separate to that needed to validate the combination product. For example, platform device-based combination products still typically require their own process settings and assembly parameters based on the specific interactions between the drug formulation, primary container and device.

Clinical supply is a key milestone for any drug development programme and should not be overlooked when planning ahead – it can be a critical mistake to assume that clinical supply will simply happen along the way to full commercial-scale manufacturing. The timespan between validating and selecting the right platform device for a drug is usually longer than programme sponsors expect, and those that properly account for it will find themselves with a significantly smoother and less stressful development journey.

"ANOTHER ASPECT OF COMBINATION PRODUCT DEVELOPMENT THAT PROGRAMME SPONSORS TEND TO UNDERESTIMATE IS THE AMOUNT OF PREPARATION REQUIRED TO REACH THE CLINIC."

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MANUFACTURING: WHERE MINOR CHANGES CAN CREATE MAJOR CONSEQUENCES

Customisability is a fundamental feature of platform devices – not only must a device be adjusted to suit the needs of the drug it is intended to deliver, pharma sponsors will often want to ensure that the final combination product is suitably aesthetically differentiated from the rest of the market, with variations in colour, label design, window size and shape, product dimensions and more. Such differentiation is not merely a branding exercise; it can help pharmacists and patients tell different injectable products apart from one another.

However, this customisability can lead to finished combination products having unique production requirements – even seemingly minor changes to the platform device's architecture can have implications for its assembly (Figure 2). Requirements arising from changes to the core platform device can include:

- Tooling updates
- Assembly machine parameter changes
- Software changes
- Force profile adjustments
- Additional validation activities.

The process is all interconnected – a decision made for usability or aesthetic reasons can lead to challenges arising during manufacturing; a packaging requirement can have knock-on effects for automation; a change to the device can affect the equipment needed for labelling. Much like validation, adopting a platform device does not make the engineering work required to turn that device into a combination product disappear. Instead, platforms move the effort away from device design towards implementation and integration of the platform device with the drug programme, and successful programmes will take this into account at an early stage and make appropriate preparations, rather than treat them as late-stage activities.

PACKAGING AND LABELLING: OFTEN OVERLOOKED, FREQUENTLY CRITICAL

Packaging and labelling are an indispensable aspect of a combination product yet are often treated as an afterthought to the device and the drug itself. It is a mistake to treat packaging and labelling as a final box to tick prior to commercialisation – they should be considered as a major aspect of combination product development and given appropriate time and care (Figure 3). Packaging and labelling can be broken down into two broad workstreams: functional and commercial/regulatory.

When talking about the functional side of packaging and labelling, the focus should be on how these aspects of the combination product affect its practical use and storage. Does the labelling influence how a user interfaces with the device? How does the label placement relate to the device's viewing window? Does the secondary packaging ensure that the device is held securely during transport and storage? These are only a few of the considerations that will need to be made to ensure that the packaging is functional – all of which require careful engineering and validation.

On the other hand, the commercial and regulatory side of packaging and labelling considers aspects such as multilingual labelling, country-specific artwork, change controls, translation management and stock-keeping unit (SKU) management. Different regulatory authorities will each have their own requirements and expectations for what is included in a device's labelling and packaging, and manufacturers must ensure that the correct SKUs are sent to the correct market. Some authorities and markets will also have expectations regarding sustainability, such as recyclability of packaging and material-use reduction.

Regulatory strategy should remain an active workstream throughout development, with ongoing engagement with relevant health authorities helping to align expectations, address emerging questions and reduce programme risk before critical milestones are reached.

Packaging and labelling are about much more than the aesthetic presentation of a combination product. They influence the usability, manufacturability and integrity of the final product, and are subject to regulatory requirements and scrutiny. Understanding what is required of packaging and labelling, how that varies across regulatory authorities and how they interact with the platform device itself are all crucial for success.



Figure 3: A platform autoinjector, being labelled on a semi-automatic labelling machine.

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CLOSING THE PLATFORM GAP

Drug delivery device development is an extraordinarily challenging process. Platform devices have gone a long way to mitigating the effort and risk required to pair a drug candidate with a suitable delivery device, making them one of the most effective routes to market for injectable therapies – especially for smaller pharma and biotech companies without their own in-house device expertise – but have not obviated that effort and risk entirely. For an injectable drug development programme to reach the market successfully, the gap between platform device and combination product must be closed. Achieving this requires a thorough understanding of the development activities that platform devices still require. As discussed, these activities include:

- Compatibility and verification
- Human factors studies
- Clinical readiness
- Manufacturing implementation
- Packaging and labelling
- Regulatory strategy and planning.

These activities are all interconnected, with decisions made in one area frequently creating requirements in another. The key to successfully navigating this complexity is a cross-functional team executing a well-controlled, phase-gated design process underpinned by risk management and robust design controls. When supported by the appropriate expertise and an ISO 13485-compliant development framework, platform adoption becomes a far more predictable and controlled pathway to market. This is where Ensera can help, combining expertise across device development, human factors, regulatory, manufacturing and packaging disciplines within a single integrated development model.

Ensera is a full-service partner that can help pharma companies smoothly navigate the turbulent waters of product and process development and minimise the risk of costly mistakes and delays. From the initial stages of platform selection through to commercial readiness, Ensera can supply the expertise to ensure that development programmes proceed according to plan and are not defined by unwelcome surprises (Box 1).

Furthermore, Ensera has established alliances and approved assembly partner status with many of the leading platform device developers, including SHL Medical (Zug, Switzerland), Ypsomed (Burgdorf, Switzerland) and Stevanato Group (Padova, Italy), in addition to fill-finish partners such as Argonaut (Carlsbad, CA, US) and American Injectables (Brooksville, FL, US). By pairing together strong relationships across the industry and a wealth of device development expertise, Ensera is ideally positioned to help its pharma partners successfully bridge the gap from platform device to approved and marketed combination product at speed.

BOX 1: ENSERA'S CAPABILITIES

Ensera helps pharmaceutical companies accelerate injectable combination product programmes by bringing device development, human factors, manufacturing and packaging expertise together within a single global organisation. The company's capabilities include:

- Design and product development support for platform and proprietary drug delivery devices
- Human factors engineering, usability studies and risk-based development
- Combination product verification, validation and regulatory support
- Final assembly of injectable combination products for clinical and commercial supply
- Secondary packaging, labelling, kitting and market-specific packaging solutions
- Integrated development-to-manufacturing programmes that reduce technology transfer risk
- Specialist support for low- to medium-volume products, including orphan and rare disease therapies
- Global manufacturing footprint across North America, Europe and Asia
- Dedicated project teams focused on responsiveness, collaboration and customer service.



Darren Hieber

Darren Hieber, Vice-President, Sales Leader USA and Alliances at Ensera, is a commercial leader with extensive experience across the pharmaceutical, biotech, CDMO, contract packaging and medical device industries. His expertise spans commercial strategy, business development, strategic alliances, injectable products, drug-device combination products, pharmaceutical packaging and outsourced manufacturing services. At Ensera, Mr Hieber leads North American sales and alliances, helping pharmaceutical and biotech companies and strategic partners navigate complex drug and device assembly, packaging and end-of-line solutions. He is passionate about building partnerships that accelerate innovation and deliver measurable value for customers.

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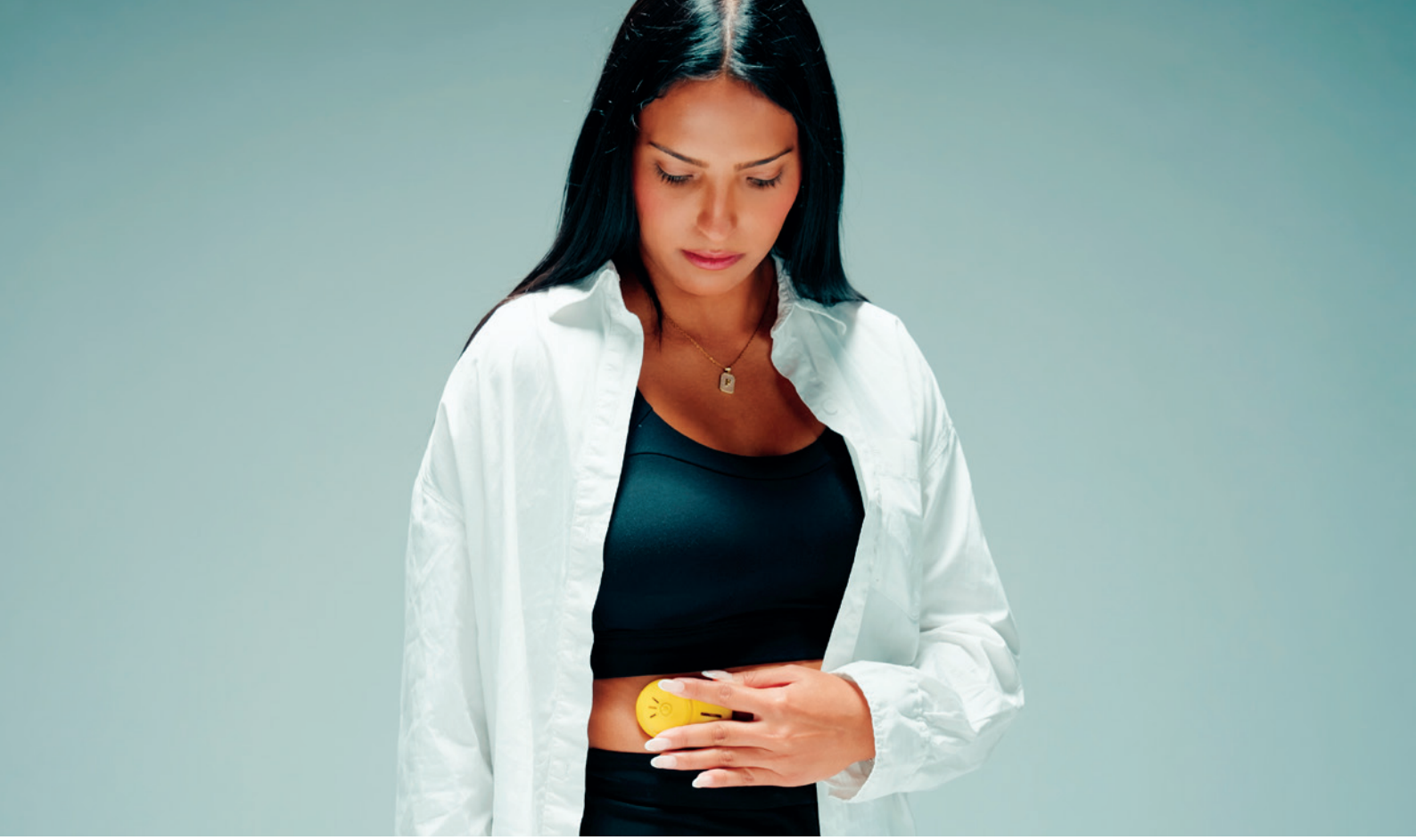
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DRUG DELIVERY DEVICES PAST AND FUTURE: A RETROSPECTIVE ON INNOVATION, ACHIEVEMENT AND HARD LESSONS

Tom Oakley of **Sanner** and **Ulrich Bruggemann** of **Takeda**

discuss the innovations that featured novel forms of drug delivery for patients, but either failed to succeed commercially or even reach the market.

The drug delivery device landscape is rich with brilliant ideas that never quite made it to patients or were launched but achieved limited commercial success. Some failed quietly in development. Others launched with fanfare only to be withdrawn. In all device categories, there are talented teams working to overcome past issues and launch better devices. Together, they form a fascinating catalogue of ambition, engineering ingenuity, patient focus, regulatory friction and market reality.

Below is a tour through the major categories of devices that have struggled to achieve their potential, explaining why they faltered and what their stories reveal about the future of drug delivery. This article was written in the spirit of learning from common challenges and educating the next generation of drug delivery pioneers. The teams behind these innovations often brought a wealth of talent and expertise.

Most of the device categories that are discussed here have involved individuals who are currently working hard to bring their devices to market or increase their market share if already on the market. Their merits or future chances of success are not discussed,

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"NEEDLE-FREE INJECTION HAS BEEN A RECURRING DREAM FOR DECADES: PAINLESS, FAST, SHARPS-FREE AND POTENTIALLY SELF-ADMINISTERED. YET RELATIVELY FEW DEVICES HAVE MADE IT TO MARKET."

rather, this is an opportunity to learn from experiences so that, together with peers across the drug delivery device ecosystem, the successful innovations can be maximised for patients to have access to devices that are increasingly effective, usable, safe and economical.

NEEDLE-FREE INJECTORS: A PERENNIAL PROMISE THAT RARELY STICKS

Needle-free injection has been a recurring dream for decades: painless, fast, sharps-free and potentially self-administered. Yet relatively few devices have made it to market. Needle-free technology has achieved most of its success in the vaccine market where healthcare professionals administer the therapy.

Challenges

- **Inconsistent Dose Delivery**: Occurs especially with viscous biologics. Dose volume can be controlled, but jet geometry and penetration depth are strongly dependent on formulation viscosity.[1] Most drug manufacturing systems control the concentration of the API or biologic. Viscosity can vary significantly because the curve of viscosity versus concentration tends to be steep and non-linear at high concentrations.
- **Skin Variability**: Age, hydration and anatomy all affect jet penetration.
- **Pain Perception**: Needle free does not mean pain free – pain studies have not convinced the market to switch to needle-free drug delivery.
- **Complexity and Cost**: Devices are often bulky, expensive, require special training and/or manufacturing processes can be more complex.
- **Non-standard Containers**: Most implementations require drug containers that are different to standard pharmaceutical cartridges and syringes. These bring risks in drug stability, filling and device verification, such as dose accuracy and free-fall tests.
- **Regulatory Caution**: Cross-contamination concerns after release of early multiuse jet injectors.

Notable Examples

- **Comfort-In (Mika Medical Co, Busan, South Korea)**: A spring-based jet-injector kit available in four countries plus the EU.[2]
- **INJEX30 (Injex Pharma GmbH, Berlin, Germany)**: Approved for use in the US, EU and China with a special focus on injecting anaesthetics for dentistry.[3]
- **Stratis and Tropis (PharmaJet, Golden, CO, US)**: Used in vaccination settings but have not yet achieved significant injector market share compared with needle-based devices.
- **Biojector**: Widely used in the 1990s and 2000s, eventually discontinued.
- **Zogenix DosePro**: Approved for sumatriptan; commercial uptake limited; discontinued product due to commercial reasons.
- **RebiJet (Merck Group, Darmstadt, Germany)**: Explored a needle-free injector for Rebif (interferon beta-1a) in the mid-2000s, which was based on the Intraject technology. It never reached commercial launch, probably due to the shift of focus to the RebiSmart reusable electromechanical injector and the Rebidose single-use autoinjector. The technology went on to become ZENEO by CROSSJECT (Dijon, France), which is still in development.[4]
- **Prime**: An electromechanical needle-free injector developed by Portal Instruments (Cambridge, MA, US), which is not commercialised yet. The company has now adopted the core technology for a needle-based reusable electromechanical autoinjector using prefilled syringes.[5]

Needle-free injectors are technologically impressive but have struggled to achieve the commercial success of needle-based injectors.

TRANSDERMAL PATCHES: THE RISE, PLATEAU AND QUIET RETREAT

Transdermal delivery had its golden era with patches developed to deliver medicines such as:

- Nicotine replacement therapy
- Pain management, e.g. fentanyl or morphine
- Contraceptives
- Hormone replacement therapy, e.g. oestrogen or testosterone
- Cardiovascular treatment, e.g. nitroglycerin
- Motion sickness reduction, e.g. scopolamine.

However, the next generation of "active" or "enhanced" patches often failed to reach the market.

Challenges

- **Skin**: A formidable barrier, especially for large molecules
- **Microneedle Patches**: Faced challenges with drug load, repeatable pharmacokinetics, manufacturing, stability, usability, skin reactions and regulatory hurdles
- **Thermal Ablation Patches**: Never scaled beyond early trials.

Notable Examples

- **Exelon Patch**: Approved in 2007 for the treatment of mild to moderate Alzheimer's disease. Developed by Novartis (Basel, Switzerland), the patch delivers the drug, rivastigmine, through the skin, offering a more convenient alternative to existing oral medications.[6]
- **Titanium Microneedle Platform (Gylden Pharma, Abingdon, UK)**: A titanium microneedle patch developed by ALZA

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(acquired by Johnson & Johnson), spun out as Macroflux, which became Zosano. Zosano had a partnering deal with Novo Nordisk (2014–2015) on insulin delivery but ultimately filed for bankruptcy in 2022 when the US FDA requested more bioequivalence data.[7] Gylden Pharma is pending regulatory approval to use the technology to deliver zolmitriptan.[8]

- **PassPort (PassPort Technologies, San Diego, CA, US)**: Uses an applicator to create microscopic porous channels in the skin before a patch is applied. The company's lead preclinical candidate is a central nervous system therapeutic in development in the US via the 505(b)(2) pathway,[9] and interim results from a Phase I trial were released in 2024.[10]
- **Iontophoretic Patches**: Various types have been launched. These drive the drug through the skin using electric fields. One example, Ionsys for delivering fentanyl, was launched in the EU and US for post-operative pain in 2006 but was recalled from the EU in 2008 due to a corrosion issue that could cause unintended fentanyl release and was withdrawn in 2009.[11] It was relaunched in some markets in 2015 then voluntarily withdrawn from the US market in 2017 for commercial reasons.[12] Most current iontophoretic patches are used for physiotherapy. They tend to be medical devices rather than combination products, and the drugs they are used for include hydrocortisone, acetic acid, dexamethasone and lidocaine. Examples are IontoPatch (Travanti Medical, Saint Paul, MN, US)[13] and IontoGo (North Coast Medical, Morgan Hill, CA, US).[14]
- **Sonophoretic Patches**: These use ultrasound to disrupt the stratum corneum and enable the drug to penetrate the skin. An example is SonoPrep from Echo Therapeutics. SonoPrep was approved in 2004,[15] but Echo pivoted towards its sonophoresis-enabled glucose monitoring platform and the company shut down in 2016.[16]

The transdermal patch field continues to attract interest, including as part of several active investigations for intradermal vaccine delivery.[17–19]

GAS-POWERED INJECTORS: ELEGANT ENGINEERING, LIMITED ADOPTION

Gas-powered autoinjectors use compressed gas (often carbon dioxide, nitrogen or argon) to drive a plunger. They offer smoother injection profiles than springs and the ability to inject viscous biologics within a reasonable injection time.

Challenges

- **Cost and Complexity**: Gas canisters add manufacturing and regulatory burden.
- **Temperature Sensitivity**: Gas pressure varies depending on ambient conditions.
- **Bulky Form Factors**: Gas-powered injectors can be larger than spring-based devices once piercers, valves and seals are included. However, gas power is typically used in applications that require more force or energy than those that can be provided by a spring, so comparisons must be fair.
- **Premium Pricing**: Needs a clear clinical advantage to justify this.

Examples that Made it to Market

- **Auvi-Q (Kaléo, Richmond, VA, US, formerly Intelliject)**: Developed to deliver adrenaline (epinephrine) for anaphylactic shock. It was launched in 2012 but recalled in 2015 due to the risk of inaccurate dose delivery.[20] It was relaunched in 2017 and the same platform is used to deliver naloxone in the Rapid Opioid Countermeasure System (naloxone) used by the US military.[21]
- The iJect/BioJect family – now discontinued.

Examples that were Cancelled

- **Ovaleap (follitropin alfa) (Teva Pharmaceuticals, Tel Aviv, Israel)**: Gas-powered injector prototypes were never commercialised
- **Bespak's Syrina and Viscala (Holmes Chapel, UK)**: Never commercialised.[22]

Examples that are in Development

- **Windgap (Watertown, MA, US)**: DualFlo, OneMix and MultiMix[23]
- **CrossJect**: ZENEO[24]
- **Altaviz (Irvine, CA, US)**: AltaVISC[25]
- **Congruence Medical Solutions (Montreal, Canada)**: Congruence Autoinjector[26]
- **SMC Ltd (Somerset, WI, US)**: Bios platform.[27,28]

Spring-based autoinjectors are difficult to beat regarding simplicity and cost for drug formulations with modest dose volumes and viscosities. Other actuator technologies, such as motors, tend to compete with gas power where large volumes or high viscosities need to be delivered.

CONNECTED DEVICES: A WAVE OF SMART TECH THAT HAS NOT YET FOUND ITS MARKET

The mid-2010s saw a surge of enthusiasm for "smart injectors", Bluetooth-enabled autoinjectors, smart inhalers, adherence trackers and cloud-connected drug delivery ecosystems (Figure 1).

Challenges

- **Low Patient Demand**: Most patients do not want or need connectivity.



Figure 1: Smart inhaler with app.

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"THE LESSON: CONNECTIVITY MUST SOLVE A REAL PROBLEM, NOT JUST ADD A FEATURE."

- **Reimbursement Gaps**: Payers rarely fund digital add-ons.
- **Device Complexity**: More components, more failure modes.
- **Timing with Respect to Drug Lifecycles**: Hard to justify connected device development at the time of drug development, or multiyear digital investments.
- **Security**: Cybersecurity and privacy concerns.

The industry has had a difficult time looking beyond the drug product, struggling with where to place the responsibility in the organisation and how to define a return on investment.

Notable Examples

- Merck Group's easypod was launched in 2007[29] and its second generation introduced connectivity with easypod Connect in 2011.[30] It continues to be on the market, and it is now in its third generation.
- Connected insulin pens have found market success with an estimated value of US$905 million (£669 million) and an estimated compound annual growth rate of 11.96%.[31] BIOCORP's (Issoire, France) Mallya and Innovation Zed's (Dublin, Ireland) InsulCheck DOSE are connected caps for a variety of disposable insulin pens. Common Sensing's (Cambridge, MA, US) Gocap insulin pen add-on became part of the Bigfoot (Milpitas, CA, US) Unity Diabetes Management System,[32] now owned by Abbott (Abbott Park, IL, US).[33] Several other connected pen caps have come and gone, one example being Timesulin (Bigfoot).
- Adherium (Melbourne, Australia) and Propeller Health developed smart add-ons for inhalers but had limited uptake. Propeller Health was acquired by ResMed (San Diego, CA, US) in 2018 then shut down. Adherium's Hailie platform is commercialised in the US with shipments of around 1,400 devices per quarter.[34]
- Teva launched the connected inhaler Digihaler for ProAir, ArmonAir and AirDuo starting in 2019 but withdrew the devices from the market in April 2024.[35]
- Bayer (Leverkusen, Germany) markets the BETACONNECT connected electronic autoinjector for Betaseron (interferon beta-1b) to treat multiple sclerosis.[36]
- There are other connected autoinjector pre-market programmes such as SHL Medical's (Zug, Switzerland) Elexy[37] and autoinjector add-ons such as Ypsomed's (Burgdorf, Switzerland) SmartPilot, which has 510(k) clearance.[38]
- Eli Lilly (Indianapolis, IN, US) is going to discontinue the Tempo™ Personalized Diabetes Management Platform at the end of 2026.[39]

The lesson – connectivity must solve a real problem, not just add a feature. The value proposition needs to be convincing and the benefits to patients and clinicians must be compelling if they are being asked to perform any actions related to connectivity.

SOLID DOSE AND POWDER INJECTION SYSTEMS: HIGH HOPES, HARD REALITIES

Solid-dose injectors and powder jet systems promised needle-free delivery of vaccines and biologics using microprojectiles or high-velocity powder streams.

Challenges

- **Dose Variability**: Especially apparent with powder dispersal. For example, one study on excised human skin membranes showed that only 50% of the powder formulation left the device and the ejected powder had significant comminution (fragmentation).[40]
- **Regulatory Uncertainty**: Novel routes raise safety questions.
- **Cold Chain and Stability Issues**: Many systems did not eliminate cold-chain needs.
- **Engineering Challenges**: Complex device mechanics.

Notable Examples on the Market

- Solid-dose implants for ophthalmic use such as ILUVIEN (fluocinolone acetonide) (Alimera Sciences, Alpharetta, GA, US), OZURDEX (dexamethasone) (AbbVie, North Chicago, IL, US), and Durysta (bimatoprost implant) (AbbVie). These are solid doses but are delivered via a needle, so they are distinct from the needle-free solid-dose injectors developed by companies such as aVaxMed (Abingdon, UK) and PowderJect.

Notable Examples in Development

- **aVaxMed**: Developer of a spring-driven solid-dose injector, formerly Glide Pharma then Enesi Pharma.

Notable Examples that have Ceased Development

- **PowderJect**: The technology injected a stream of dry powder particles. It was discontinued before reaching the market, probably due to the changing competitive environment. In the late 1990s disposable syringes improved, needlestick protection systems became more widely adopted, autoinjectors became common and needle-based vaccine administration remained inexpensive.

Lessons can be learned from the experiences of solid-dose injectors. Solid doses are a compelling option when extended release is required, for example, in ophthalmic implants. For other applications such as vaccines, the value proposition must be convincing when compared with needle-based liquid injections, especially in the modern era where cold-chain distribution and needlestick protection have improved greatly.

INHALED BIOLOGICS: THE EXUBERA EFFECT AND ITS AFTERMATH

Inhaled insulin was once heralded as the future of diabetes care. If inhaled insulin had been successful, then it would have paved the way for many more inhaled systemic biologics. Instead, it became a cautionary tale.

Challenges

- **Pulmonary Safety Concerns**: Long-term effects of inhaled proteins remain uncertain.

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- **Variable Absorption**: Affected by lung function, technique and comorbidities.
- **Large Devices**: Notably for Exubera, less so in other cases such as Afrezza (Mannkind Corporation, Danbury, CT, US)
- **Price**: Cost and reimbursement challenges
- **Established Alternatives**: Competition from improved injectable pens and pumps.

Notable Examples

- **Exubera (Pfizer)**: Launched 2006, withdrawn 2007.
- **Afrezza**: Available on the market but not yet a blockbuster at US$75 million sales per year.[41]
- **Eli Lilly-Alkermes AIR Insulin System**: This reached Phase II trials.
- **Novo Nordisk-Aradigm AERx iDMS**: A liquid-based insulin system which reached Phase III trials. The liquid strips and complex electronic device would have led to high goods costs.
- **Inhaled Glucagon-like Peptide-1s and other Biologics**: Multiple programmes discontinued.

The lungs are a promising but unforgiving route. Dry powder inhalers have limits around dose mass and drug suitability for micronisation. Pressurised metered dose inhalers present formulation challenges with approved propellants. Nebulisers do not have these drawbacks and can be used in Phase I and II trials onwards, but a successful platform needs to support easy adaptability to the given drug formulation and viscosity (Figure 2).

OBIs: A CATEGORY WITH SUCCESSES AND HIGH POTENTIAL BUT SEVERAL CASUALTIES

On-body injectors (OBIs) – also called "patch pumps", "on-body delivery systems", or "bolus injectors" – are designed for self-administration of large-volume biologics, ideally negating the need for patient visits to infusion centres. This device category has seen some notable successes and shows that new device categories are possible



Figure 3: Injector examples.



Figure 2: A variety of inhalers used for drug delivery.

if the clinical need is present, the technology is not too risky and the regulatory pathway is similar to that of other successful device formats (Figure 3).

Challenges

- **Attachment to the Body**: Skin adhesion or reaction issues
- **User Anxiety**: Patients uncomfortable wearing a device for more than a few minutes.
- **Complexity and Cost**: More components than prefilled syringes or autoinjectors.
- **Manufacturing Challenges**: Sterility, assembly and reliability
- **Drug Device Integration Issues**: Especially with viscous or sensitive biologics.
- **Unfamiliarity and Perception**: Technology and patient adoption with stakeholders.

Notable Examples of Devices that have Reached the Market

- **West Pharmaceutical Services' (Exton, PA, US) SmartDose**:
  - Launched then discontinued in the 3.5 mL variant for Amgen's (Thousand Oaks, CA, US) Repatha (evolocumab).[42,43] Patients were advised to switch from using one OBI to three autoinjectors.[44]
  - Launched for AbbVie's Skyrizi (risankizumab) in 2020. AbbVie acquired manufacturing and supply rights to SmartDose 3.5 mL in January 2026.[45]
  - Approved in 2022 but never launched for Alexion's (Boston, MA, US) ULTOMIRIS (ravulizumab).
  - The 10 mL variant was approved in the US in October 2022 for scPharmaceuticals' (Lexington, MA, US) FUROSCIX (furosemide injection) to treat congestive heart failure. It delivers 80 mg of FUROSCIX over five hours.[46]

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- **Neulasta (pegfilgrastim) Onpro (Amgen):**[47] Delivered using an Insulet OBI. At the time of writing, more than 1 million patients have used Neulasta Onpro.
- **EMPAVELI-enFuse (pegcetacoplan):** Based on the enFuse platform by Enable Injections (Cincinnati, OH, US), approved by the FDA in 2023.[48]
- **UDENYCA (pegfilgrastim-cbqv)-Sorrel:** Uses the Sorrel (LTS Lohmann, Andernach, Germany) platform[49] and which was launched in 2024.
- **Lasix ONYU (furosemide injection)-SensAir:** Uses a Gerresheimer (Düsseldorf, Germany)[50] OBI, approved by the FDA in 2025.

Notable Examples of Devices in Development

- Prefilled, single-use OBIs such as BD's Libertas[51] and Ypsomed's YpsoDose[52]
- Part-reusable motor-driven OBIs such as Stevanato Group's (Padova, Italy) Vertiva[53] and Nemera's (La Verpillère, France) Symbioze[54]
- Subcuject's osmosis-driven OBI.

Several OBIs have been discontinued, such as Ratio's (Madison, WI, US) hydrogel-powered injector or Bespak's gas-powered Lapas.

NASAL DELIVERY OF BIOLOGICS: CAN BE FAST AND SIMPLE, BUT VARIABLE

Nasal delivery has been successful for small molecules (e.g. naloxone, sumatriptan, adrenaline) but attempts to expand into biologics and vaccines have been rocky.

Challenges

- Mucociliary clearance – the drug is swept away quickly
- Limited absorption of large molecules
- Irritation and tolerability issues
- Device variability means the spray plume geometry, delivered dose and droplet size distribution depend on pump pressure (therefore typically the force provided by the user), nozzle tolerances and formulation properties (viscosity and surface tension for liquids, particle morphology and electrotribology for dry powders).

Notable Examples

- **Nasal Insulin Programmes:** Multiple discontinued.
- **Nasal Vaccines:** Many candidates failed to show adequate immunogenicity, but FluMist (MedImmune, Gaithersburg, MD, US), which uses influenza virus subtypes A and B, received FDA approval first in 2012 and in 2024 for self- or caregiver-adminstration.[55]
- Baqsimi (Amphastar Pharmaceuticals, Rancho Cucamonga, CA, US) is glucagon delivered by Aptar's (Louveciennes, France) Unidose powder device.[56]
- NOSA (Stockholm, Sweden) and Hogne (Nacka, Sweden) TrigeNas nose plugs are in development.

Nasal delivery remains attractive but technically unforgiving.

WHY SO MANY DEVICE CATEGORIES STRUGGLE

Across categories, the same patterns recur.

Biology Beats Engineering

The human body is not a passive receptacle. Skin, lungs, nasal mucosa and subcutaneous tissue all impose constraints that clever engineering cannot always overcome.

Simplicity Wins

Patients, clinicians and payers gravitate towards devices that are small, intuitive and involve minimal use steps. Devices must also be reliable, have low risks, costs and technological complexity. Anything more complex must deliver a clear clinical benefit.

Integration is Difficult

Drug-device combination products require the right timing for market pull, technology push, the speed-to-market to stay ahead and the pharmaceutical company to need the product just at the right time. They also need compatible stabilities and regulatory co-ordination with the preferred technology already approved by a regulatory agency. Manufacturing harmonisation is also required, for example, using a standard primary container that enables reuse of filling technology and provides potential as platform technology. Many programmes fail at these stages.

The Market is Ruthless

Even technically successful devices can die if reimbursement is weak, training burden is high, competitors launch simpler alternatives or the target population is small.

Adoption Takes Time

Successful launches of products by start-up companies tend to take more than 10 years. For example, Kaléo was founded in 2000 and launched Auvi-Q in 2012.[57,58] Sensile Medical (now part of Gerresheimer) was founded in 2004 and launched the D-MINE pump in 2019,[59] and Enable Injections was founded in 2010 and launched enFuse in 2023.[60]

WHAT WE CAN LEARN ABOUT THE FUTURE

Despite the challenges, innovation and evolution in drug delivery devices continue at pace. The next generation of devices will likely succeed if they:

- Solve a real clinical or workflow problem
- Reduce burden, rather than adding features
- Integrate seamlessly into existing care pathways
- Demonstrate clear economic value
- Apply to diverse patient populations
- Get the right fit and timing for market pull and technology push
- Provide advantage over competitor devices
- Address why similar technologies struggled.

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WHERE CONTENT MEETS INTELLIGENCE ONdrugDELIVERY

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2026/27 Editorial Calendar

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END-OF-DOSE CLICK-BAIT: HARDER THAN IT SOUNDS

Peter McGrattan of **Team Consulting**

focuses in on the particular challenge of engineering an end-of-dose click for autoinjectors, examining the key design tensions, increasing regulatory attention, the trade-offs between different power mechanisms and how potential alternative feedback mechanisms may play into the design.

Engineering the "perfect" end-of-dose click has long been recognised as a deceptively difficult challenge. While often viewed as a relatively small feature, the ability to generate a reliable and meaningful end-of-dose indication can be strongly influenced by the wider device architecture. As injectable therapies become increasingly commonplace, driven in part by the rise of glucagon-like peptide-1 (GLP-1) products, and device requirements continue to evolve towards larger volumes, longer injections and more demanding delivery profiles, this seemingly simple challenge has only become more relevant.

End-of-dose clicks can play a critical role in helping users identify when dose delivery is complete, reducing the risk of premature device removal resulting in an incomplete delivery. As regulators place increased focus on essential drug delivery outputs, end-of-dose indication is increasingly being treated as a critical aspect of device performance that must be understood, characterised and assessed. However, defining, designing and validating an acceptable click is not straightforward. A click that is clearly audible during laboratory testing may be far less noticeable during real-world use, making it essential to assess click performance in representative conditions early in development.

With rising demand for powered injectors, including both autoinjectors and on-body devices capable of delivering larger volumes and more viscous drugs, longer injection times are becoming

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increasingly common. As delivery times increase, users become ever more reliant on clear, unambiguous feedback to know when dosing is complete. In some cases, a traditional end-of-dose click may no longer be sufficient, making alternative forms of user feedback increasingly relevant.

While the challenge of creating reliable end-of-dose feedback remains, today's device architectures introduce a new question: how can the mechanism used to generate end-of-dose feedback influence the architecture of a powered injection device itself? As the industry moves beyond traditional spring-powered systems in pursuit of accommodating increasingly demanding drug products, end-of-dose feedback is becoming more than a usability consideration – it is increasingly shaping fundamental architectural decisions that can ultimately affect patient error, device complexity and treatment effectiveness.

TIMING SENSITIVITY

Human factors teams will often, understandably, want the end-of-dose click to indicate that delivery is complete and the device is safe to remove. In practice, this can be deceptively difficult to achieve. The reason is that, to trigger a click, something generally has to be moving. To ensure robust performance against manufacturing variation, the trigger will typically be actuated while the plunger is still moving. At that moment, the drug may still be flowing and delivery is therefore not yet complete.

This is one reason that users are often instructed to wait for a period after hearing the click before removing the device. That hold time effectively compensates for variability in manufacturing tolerances, friction, fluid properties and delivery dynamics. As a result, it must generally be longer than required for most individual devices to ensure robust performance across the wider product population.

Demonstrating that this margin remains adequate under all foreseeable conditions can be challenging. Towards the end of delivery, available drive energy and flow rate may be at their lowest, while visual cues, such as plunger movement, become increasingly subtle. These effects are particularly significant for high-viscosity, low-flow-rate systems, where relatively small changes in viscosity, friction or available energy can disproportionately affect the final stages of delivery. This creates a fundamental timing trade-off (Figure 1):

- Trigger the click too early and the user may remove the device before delivery is complete
- Trigger it too late and friction, tolerance stack-up or an exhausted energy budget may prevent it from occurring at all.

> "THE GOAL IS NOT SIMPLY TO GENERATE A CLICK, BUT TO GENERATE ONE AT THE RIGHT MOMENT, EVERY TIME."

The goal is not simply to generate a click, but to generate one at the right moment, every time. Whether that is achievable depends heavily on the underlying device architecture and, perhaps most importantly, where the energy for that feedback comes from.

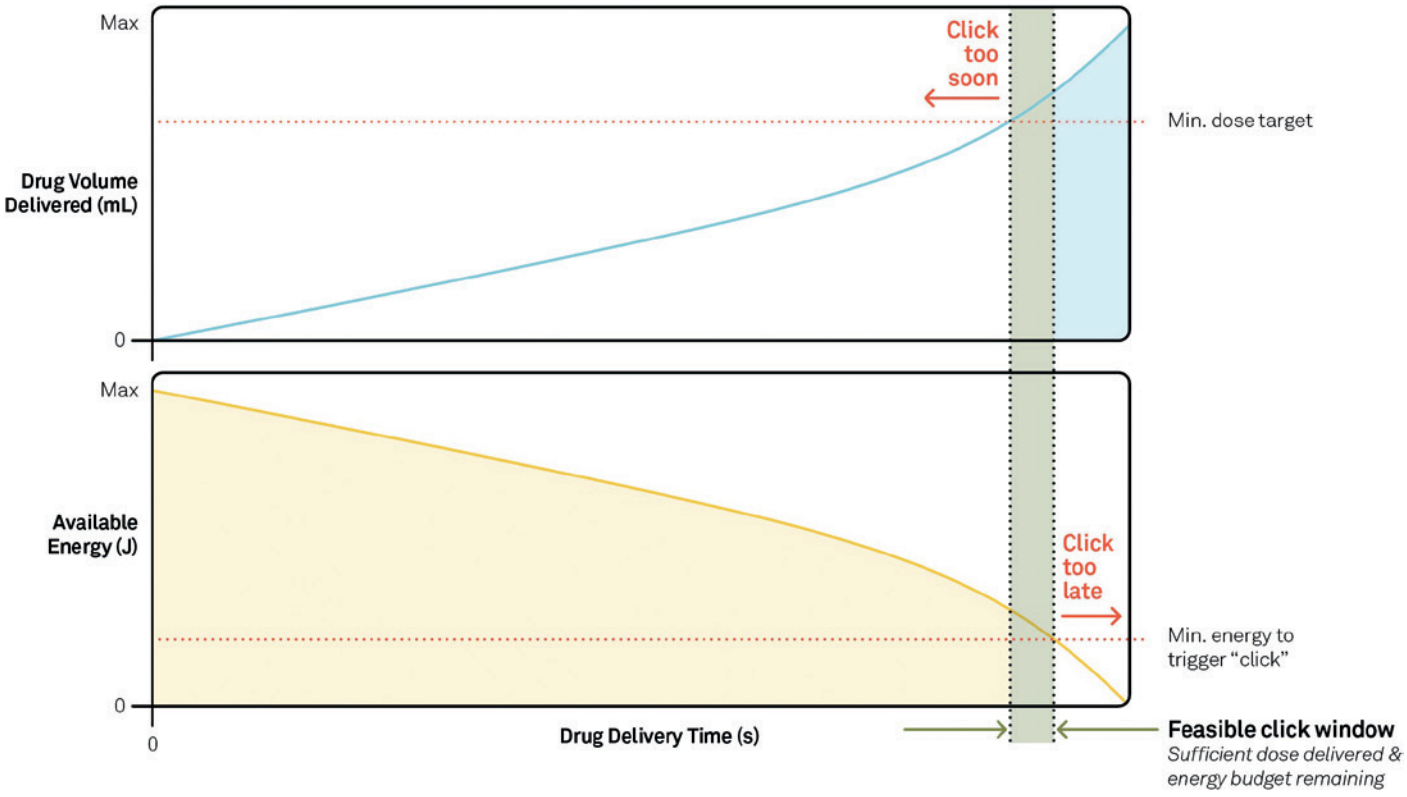


Figure 1: Visualising the challenge of timing an end-of-dose click.

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"IN THEORY, THESE APPROACHES CAN OFFER GREATER DELIVERY CAPABILITY FOR A GIVEN DEVICE SIZE WHILE REDUCING RELIANCE ON HIGHLY STRESSED COMPONENTS REQUIRED TO RETAIN LARGE SPRING LOADS OVER EXTENDED PERIODS."

CLICK OR TWIST?

For decades, spring-powered autoinjectors have dominated the injection-device landscape. More recently, gas-powered and electromechanical architectures have emerged that may be better positioned to support the move towards larger volumes and longer injection durations. In theory, these approaches can offer greater delivery capability for a given device size while reducing reliance on highly stressed components required to retain large spring loads over extended periods.

But what impact do these alternative energy sources have on end-of-dose feedback? Do they offer meaningful advantages over traditional spring-powered systems, or do they simply introduce a different set of engineering and usability challenges?

Gas-Powered Systems: A Click and a Hiss?

Gas-powered systems can offer significantly greater delivery capability for a given device size. From an end-of-dose feedback perspective, this can also appear attractive. Unlike spring-powered systems approaching full extension, there may still be substantial energy available to generate a noticeable click at the end of delivery.

However, the timing challenge does not disappear – it may even become more complex. Gas venting often needs to begin before delivery is truly complete, meaning any end-of-dose trigger must either occur while the drug is still flowing or rely on an additional mechanism that operates after delivery has ended. In this sense, the architecture changes the problem rather than eliminates it.

Gas-powered systems can also introduce more prominent competing sounds. A click generated during or shortly after gas venting may need to compete with an accompanying hiss. Unlike the familiar click associated with many mechanical devices, patients may have little prior experience interpreting such sounds as indicators of dose completion. As a result, designers may be more inclined to supplement or replace audible indicators with tactile or visual feedback mechanisms.

Electromechanical Systems: Click by Choice or Consequence?

Electromechanical systems present a different set of opportunities and challenges. Unlike spring- and gas-powered architectures, the end-of-dose indication need not be directly coupled to the delivery mechanism itself. However, motors and drive systems often generate a range of noises throughout delivery, meaning that there may already be a number of clicks and buzzes to contend with before any deliberate end-of-dose feedback is introduced. These competing signals may need to be managed to ensure that the intended feedback remains clear and unambiguous.

With sufficient battery capacity remaining, designers have considerable freedom to generate audible, tactile or visual feedback at dose completion. This flexibility can be attractive from a user-feedback perspective, although the associated complexity and cost often make such systems better suited to reusable platforms than disposable devices.

Spring-Powered Systems: Better the Devil You Know?

Spring-powered systems offer some obvious advantages. The relationship between stored spring energy and delivery performance is well understood, making these devices highly predictable, simple and cost-effective. Unsurprisingly, they remain the dominant architecture for single-use injection devices. However, spring-powered systems also present some particular challenges when it comes to end-of-dose feedback.

As already discussed, managing feedback close to dose completion becomes increasingly difficult because the available spring energy is approaching its minimum. In many devices, the prominence and reliability of the click are therefore closely linked to how that remaining energy is managed. Various delayed-click mechanisms have been introduced to overcome these limitations by storing and releasing energy independently of the delivery spring. While effective, these approaches add parts, complexity and cost, and may also introduce additional timing sensitivities of their own.

Choosing the Right Power Source

It is clear that no power source completely solves the end-of-dose feedback problem. Spring, gas and electromechanical systems simply shift the balance between timing, energy availability, complexity and cost. While electromechanical systems may offer the greatest freedom to generate deliberate feedback events, their cost clearly favours reusable platforms. For disposable devices, the humble spring-powered click remains difficult to beat for simplicity, while gas-powered systems may offer a more favourable energy budget for a given form factor.

Ultimately, the decision should come down to the requirement and what is considered acceptable. After all, feedback is not free. Is the goal the click of a computer mouse or a torque wrench? And what impact do the energy, space and complexity required to achieve that feedback have on other aspects of device performance, from delivery capability to the risk of premature device removal?

ENGINEERING THE PERFECT CLICK

Engineering the perfect end-of-dose click remains anything but a simple design challenge. Today, designers have a wide range of device architectures, energy sources and feedback mechanisms to consider. End-of-dose, and even dose progression feedback, may be delivered through a traditional mechanical click, gas venting, a deliberate electromechanical event or visual and tactile indicators.

However, these alternatives do not necessarily solve the click challenge.

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They simply provide different ways of tackling it. Reliability, timing and user interpretation remain critical, while competing sounds, delivery dynamics and the interaction between the drug product and device architecture continue to influence how feedback is perceived. As injection volumes and viscosities increase, flow rates may decrease and delivery durations extend, reducing the prominence of traditional end-of-dose indicators and increasing the potential for user uncertainty.

The rapid growth of frequently administered injectable therapies, including GLP-1 products, is increasing the scrutiny on device cost, material use and sustainability. A dedicated delay mechanism may improve the timing and prominence of a click, but it can also add parts, complexity and waste to a single-use device. Reusable platforms may make that investment or inclusion of electronics easier to justify, yet they must deliver clear, consistent feedback across a potentially broader range of drug products and delivery profiles.

"A DEDICATED DELAY MECHANISM MAY IMPROVE THE TIMING AND PROMINENCE OF A CLICK, BUT IT CAN ALSO ADD PARTS, COMPLEXITY AND WASTE TO A SINGLE-USE DEVICE."

End-of-dose feedback should therefore be considered early in development, not retrospectively justified at the end. Energy budgeting, tolerance analysis, sensitivity studies and focused subsystem testing can all help to determine whether the intended feedback will remain sufficiently prominent and reliable across manufacturing variation and foreseeable use conditions.

Whether the chosen solution is spring-driven, gas-powered or electromechanical, the feedback mechanism must ultimately be considered as part of the wider device architecture. Understanding the interaction between the user, drug product, delivery system and manufacturing process capability is essential to reducing the risk of premature device removal, incomplete delivery and ineffective treatment.

When something as seemingly simple as a click can be the difference between effective and ineffective treatment, it should not be left until the later stages of development. A poorly optimised end-of-dose signal can lead to longer-than-necessary hold times for frequently administered therapies or the need for additional electronics and visual indicators to achieve the required user confidence. It should be there in the very first series of napkin sketches.



Peter McGrattan

Peter McGrattan is a Senior Engineering Consultant at Team Consulting, having joined in 2019. As a technical lead, he is responsible for guiding the development of complex drug delivery devices from concept through to commercialisation. He works closely with clients and multidisciplinary teams to tackle challenging engineering problems, manage technical risk and deliver robust, manufacturable products.

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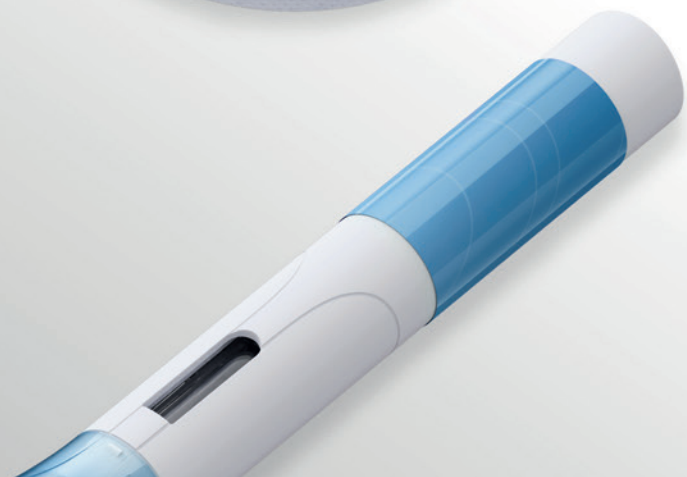
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Expert View

PLATFORMS IN BIOPHARMA DEVICE DEVELOPMENT: FROM PRACTICE TO STRATEGY

Tim Quigg and **Katie Ogden** from Crux Product Design, with **Dr Shirish Ingawale** from Takeda, discuss some of the key points from the 2026 PFS & Injectable Drug Devices East Coast Conference regarding biopharma platform technology.

Platform approaches have become an increasingly important strategy in drug-device combination product development. As pipelines expand, development timelines compress and pressure mounts to reduce cost and complexity, while pharmaceutical organisations search for ways to harness common device, container and development architectures across multiple products.

At the PFS & Injectable Drug Devices East Coast Conference in April 2026 (SAE Media Group, Boston, MA, US), discussions revealed and reinforced an industry that broadly believes in the promise of platform devices but continues to face significant challenges in their implementation. A central tension was highlighted – while platforms offer speed, efficiency, knowledge reuse and scalability, they must also accommodate increasingly diverse drug products, evolving patient needs and changing regulatory expectations. Success depends not only on technology but also on organisational alignment, strategic investment and collaboration across the ecosystem.

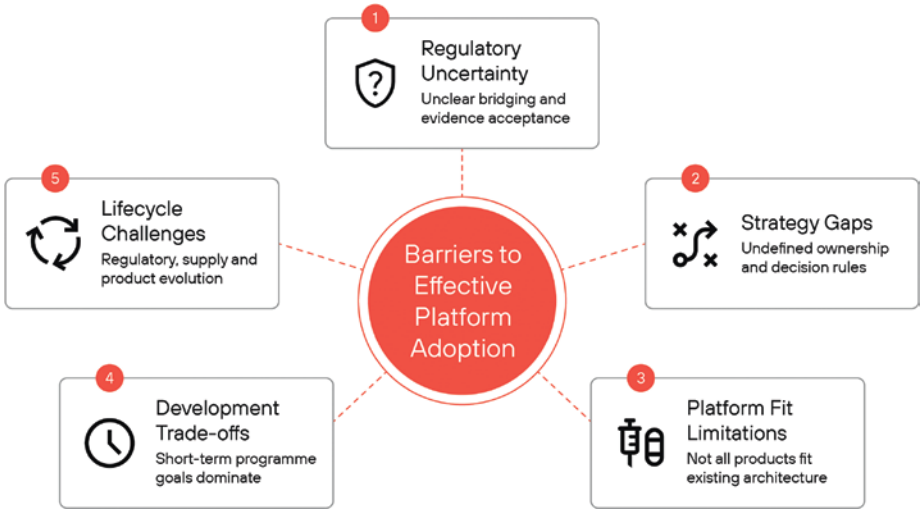


Figure 1: Barriers limiting effective platform adoption today.

LESSONS FROM CURRENT PLATFORM USE – WHERE THE INDUSTRY STANDS TODAY

Most organisations have already adopted some degree of platform thinking, particularly around primary containers, fill-finish systems, capital expenditure, process engineering and delivery devices. However, adoption across the industry is far from uniform.

In many companies, platforms have evolved organically rather than through deliberate enterprise-wide strategies. As a result, teams often use the term "platform" differently, creating uncertainty around ownership, intended scope and expected benefits. While some view a platform as a reusable (used across two or more drug assets) device architecture, others consider it in broader terms, encompassing the container, formulation technologies, manufacturing processes and even supporting documentation. Despite these differences, there is broad agreement that platforms can significantly improve development efficiency when implemented effectively.

WHAT ARE THE BARRIERS LIMITING EFFECTIVE PLATFORM ADOPTION TODAY?

Regulatory Uncertainty and Shared Risk

A recurring theme was the lack of regulatory clarity regarding platform approaches. While many companies hope to use existing testing and validation data across multiple products, questions remain regarding the extent to which regulators will accept bridging strategies and platform-based evidence (Figure 1).

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The risk is amplified because platform failures have broader consequences. A defect, design issue or regulatory challenge affecting a platform could impact multiple products simultaneously, creating significant portfolio-level exposure. This often makes organisations cautious about their commitment to platform approaches.

Lack of Clear Platform Strategy

The discussions highlighted uncertainty around platform governance, with questions including:

- What qualifies as a platform?
- Who owns platform decisions?
- When should programmes adopt or deviate from a platform?
- How should success be measured?

Without clear strategies and decision-making frameworks, platform initiatives can struggle to gain full organisational support. Development teams often prioritise immediate, product-specific objectives over longer-term platform goals.

Platform Fit Limitations

One of the greatest technical challenges is that no two drug products are identical. Variables such as viscosity, volume, stability requirements, delivery requirements, target patient populations and material compatibility may push products beyond the boundaries of an existing platform.

Participants described the challenge as attempting to fit a square peg into a round hole. While standardisation is desirable, some therapies require specialised solutions that cannot easily conform to a pre-existing architecture, which can create tension between platform efficiency and product optimisation.

Time and Development Trade-Offs

Successful platforms often require significant upfront investment. Defining design spaces, validating platform performance, generating supporting data and understanding platform limits all require time and resources. However, development teams are often incentivised to deliver individual products quickly. As a result, teams frequently choose short-term programme needs over broader platform development objectives. What benefits the organisation in five years may not align with what delivers the next regulatory submission fastest.

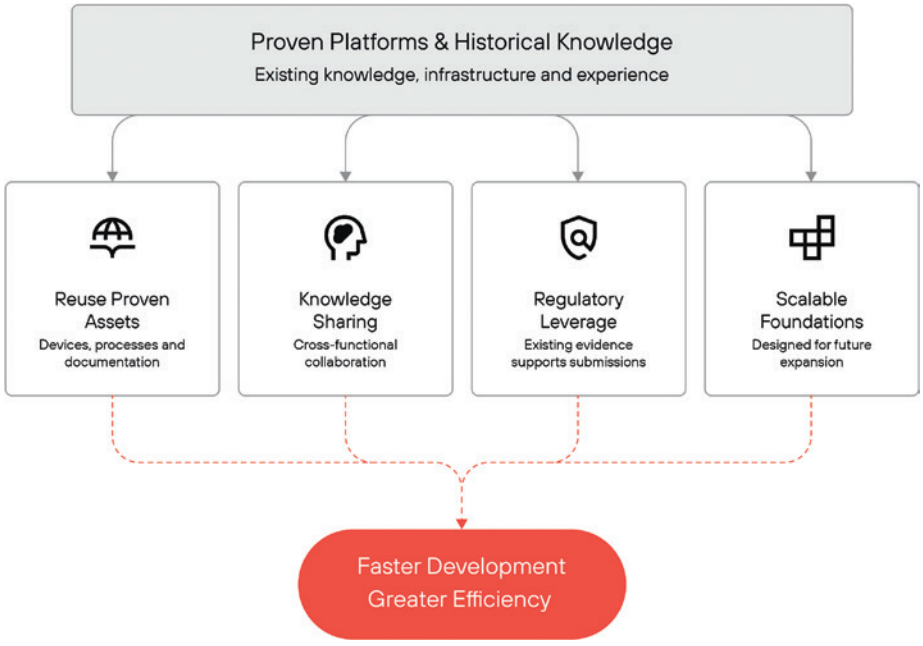


Figure 2: Factors driving successful platform adoption.

Lifecycle and Execution Challenges

Platforms are not static and, with product evolution, organisations face ongoing challenges, such as lifecycle management, new regulatory requirements, emerging and unmet patient needs, supply chain changes and post-approval modifications.

Many conference participants noted that format transitions, such as moving from vial to prefilled syringe and eventually to an autoinjector, have effectively become standard practice. These transitions can challenge original platform assumptions and require substantial rework if flexibility was not designed in from the outset.

WHAT IS WORKING TODAY?

Speed and Efficiency Gains

The strongest argument for platforms is their ability to accelerate development (Figure 2). Established platforms allow teams to reuse known processes, reduce duplicate testing, minimise engineering effort, streamline manufacturing and improve predictability. Rather than starting each programme from scratch, organisations can build on proven foundations, shortening development timelines and reducing risk.

Reuse of Proven Platforms

Increasingly, organisations are using existing container systems and manufacturing infrastructure, along with their accompanying design verification protocols, technical documentation and historical development knowledge. This reuse reduces duplication and helps companies capture the value of previous investments. Participants highlighted that proven "workhorse" devices often deliver substantial benefits across numerous programmes.

Cross-Functional Alignment and Knowledge Sharing

Successful platforms depend heavily on collaboration. Conference participants emphasised the importance of bringing together:

- Formulation scientists
- Device engineers
- Regulatory specialists
- Manufacturing teams
- Commercial stakeholders.

Shared technical knowledge creates shared confidence. Companies that actively capture and distribute platform learnings are better positioned to make informed decisions and avoid repeating past mistakes.

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Regulatory Understanding

Although regulatory uncertainty remains a concern, established platforms can provide meaningful advantages. When organisations have robust historical data, established validation strategies and clearly defined design spaces, regulatory submissions become more predictable. Existing evidence can support future programmes and reduce the amount of new data required.

Scalable Platform Foundations

The most successful organisations are building platforms designed for expansion rather than immediate programme needs alone. By creating broader design spaces and establishing reusable development frameworks, companies can position themselves to support future products more efficiently while maintaining flexibility.

OVERCOMING BARRIERS: WHAT ARE THE CHALLENGES TO SCALING PLATFORMS?

Upfront Investment Constraints

The business case for platform investment remains a major challenge. Significant investment in platform infrastructure is often required before a specific product can justify the cost, which can make it difficult to secure funding, especially within organisations focused on programme-level returns (Figure 3). Many conference participants recognised that platform investment frequently competes with immediate product-development priorities.

Future Uncertainty and Design Risk

Designing platforms for future products requires predicting requirements that may not yet exist. Organisations must decide:

- How broad the design space should be
- Which parameters are worth accommodating
- How much flexibility is necessary.

Over-engineering creates unnecessary complexity and cost. Under-engineering may restrict future adoption. Finding the balance remains one of the industry's biggest challenges.

Platform Rigidity Versus Portfolio Needs

Platforms can unintentionally constrain innovation. In some organisations, large investments create pressure to force products onto existing platforms even when alternative approaches may provide better outcomes. Platform strategies must therefore be sufficiently flexible to accommodate therapies that genuinely require unique solutions; standardisation should enable innovation, not restrict it.

"PLATFORM STRATEGIES MUST THEREFORE BE SUFFICIENTLY FLEXIBLE TO ACCOMMODATE THERAPIES THAT GENUINELY REQUIRE UNIQUE SOLUTIONS; STANDARDISATION SHOULD ENABLE INNOVATION, NOT RESTRICT IT."

Regulatory and Cross-Programme Risk

As platform adoption expands, so does potential exposure. Changes in regulatory expectations could impact multiple products sharing a common platform at once. Likewise, quality or performance issues may create portfolio-wide consequences. This "eggs all in one basket" risk continues to influence platform decision-making across the industry.

Alignment and Collaboration Barriers

Delegates repeatedly identified organisational alignment as one of the most significant challenges. Platform success requires agreement across departments, functions and leadership teams. Without a shared vision, platform initiatives often struggle to maintain momentum or secure consistent support.

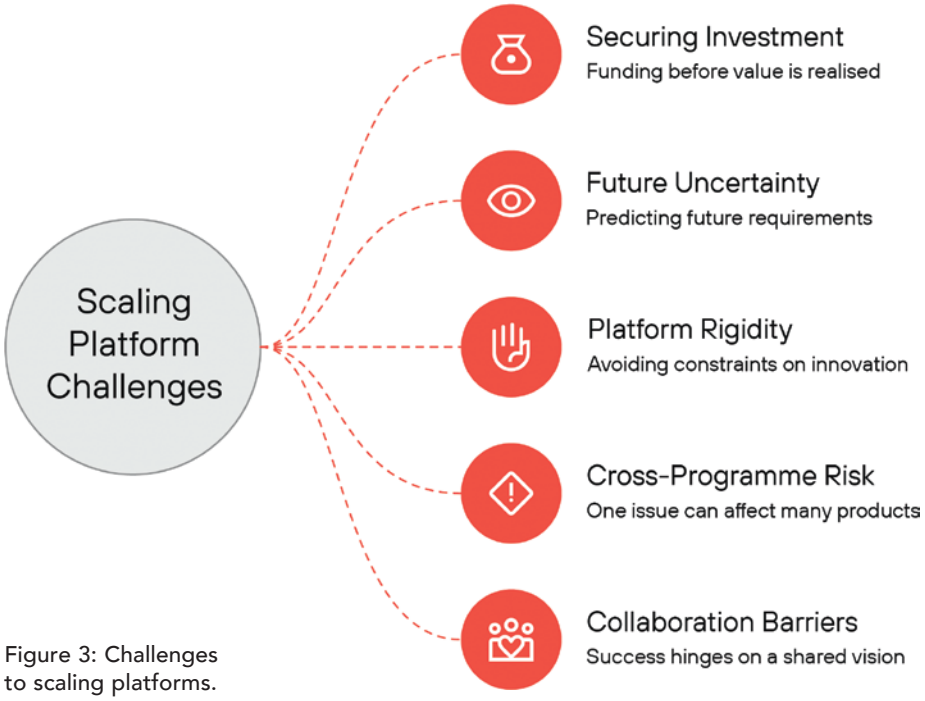


Figure 3: Challenges to scaling platforms.

OPPORTUNITIES FOR NEXT-GENERATION PLATFORMS

Modular and Scalable Architectures

The strongest future vision to emerge from the discussions was modularity. Rather than creating rigid platforms, organisations increasingly see value in configurable systems consisting of reusable building blocks (Figure 4). These architectures could support:

- Multiple primary containers
- Different patient populations
- Various drug products
- Future design evolution.

The key message was that modularity enables reuse without sacrificing flexibility.

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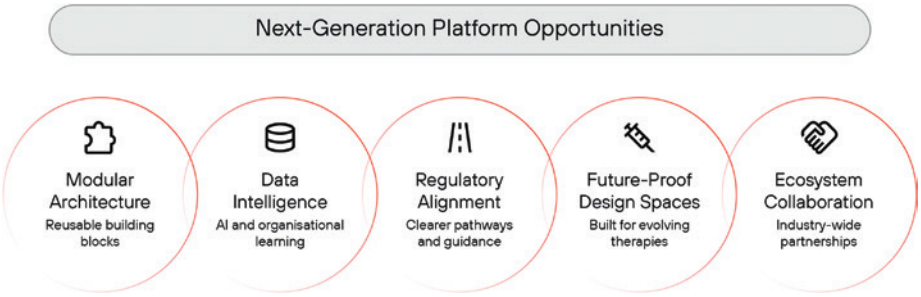


Figure 4: Opportunities for next-generation platforms.

Data-Driven Platform Intelligence

Delegates recognised a significant opportunity to use data more effectively, believing that future platform development could benefit from structured internal databases and historical testing repositories. Nearest-neighbour analyses, shared organisational learning, predictive modelling and artificial intelligence-driven insights could also be beneficial. Rather than repeatedly generating similar knowledge, companies can develop increasingly intelligent platform ecosystems that improve decision-making over time.

Regulatory Alignment and Acceptance

A future state where regulators are more comfortable with platform approaches was viewed as a potential major accelerator of adoption. Possible improvements include:

- Clear regulatory pathways
- Platform-specific guidance
- Defined bridging expectations
- Drug-product-agnostic approaches
- Greater agency engagement.

As precedent grows, confidence in platform-based submissions is expected to increase.

Expanded and Future-Proofed Design Spaces

Delegates advocated for defining platform design spaces more broadly from the outset, and rather than optimising narrowly around current requirements, the general consensus was that future platforms should anticipate new formulations, emerging therapies, paediatric applications, higher viscosities and new delivery paradigms. Building flexibility into the platform at an early stage may significantly reduce future redevelopment needs.

Ecosystem Collaboration

Perhaps the most transformative opportunity discussed was greater collaboration across the industry, with delegates envisioning stronger partnerships between:

- Drug developers
- Device manufacturers
- Packaging suppliers
- Regulatory bodies
- Industry associations.

"GREATER ECOSYSTEM COLLABORATION COULD ACCELERATE LEARNING, REDUCE DUPLICATION AND HELP ESTABLISH COMMON STANDARDS THAT BENEFIT THE ENTIRE SECTOR."

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Some even proposed more open sharing of platform knowledge and lessons learned. Greater ecosystem collaboration could accelerate learning, reduce duplication and help establish common standards that benefit the entire sector.

THE ROAD AHEAD

Discussions at the conference revealed an industry undergoing a fundamental shift from project-centred development towards platform-centred thinking. Today, organisations clearly recognise the benefits of platforms – faster development, lower costs, reduced risk, more consistent user experiences and improved scalability. These benefits, however, remain difficult to capture consistently because of regulatory uncertainty, organisational silos, investment challenges and concerns about platform flexibility.

The future appears increasingly centred on modular, data-driven platforms supported by stronger governance and broader collaboration. Organisations that define clear platform strategies, invest in reusable knowledge, establish cross-functional ownership and engage proactively with regulators are likely to gain significant advantages.

Most importantly, the conversations suggest that platform development is no longer simply an engineering exercise – it is becoming a strategic capability. The companies that succeed will be those that can balance standardisation with flexibility, use data to expand platform boundaries intelligently and invest ahead of immediate programme needs. By doing so, they will not only accelerate individual product launches but also create sustainable development ecosystems capable of supporting the next generation of biopharmaceutical innovation.

ABOUT THE COMPANIES

Crux Product Design is a technology-driven consultancy specialising in drug delivery and healthcare innovation. The company partners with pharmaceutical companies to develop inhalers, injection devices, wearables and novel delivery systems. Its multidisciplinary team combines engineering, sciences, human factors and design expertise to turn complex challenges into successful products, certified to ISO 13485, ISO 9001 and ISO 14001 standards, as well as an Ecovadis Platinum rating.

Takeda is a global biopharmaceutical company delivering a pipeline of therapies that patients urgently need. Together with its partners, Takeda is focused on advancing the patient experience and creating new standards of care. Its technology-forwards, human-centric approach aims to expand the difference it makes for patients and communities.



Tim Quigg

Tim Quigg, Development Director at Crux Product Design, supports development strategy and novel problem solving across drug delivery device development programmes. Crux collaborates with 18 of the top 20 pharmaceutical companies, providing Mr Quigg with foresight into cross-industry challenges. With a Masters in Mechanical Engineering and a career spanning both combination product and medical device development, he champions front-loading of technical understanding, using emerging tools to de-risk design, development and commercialisation.

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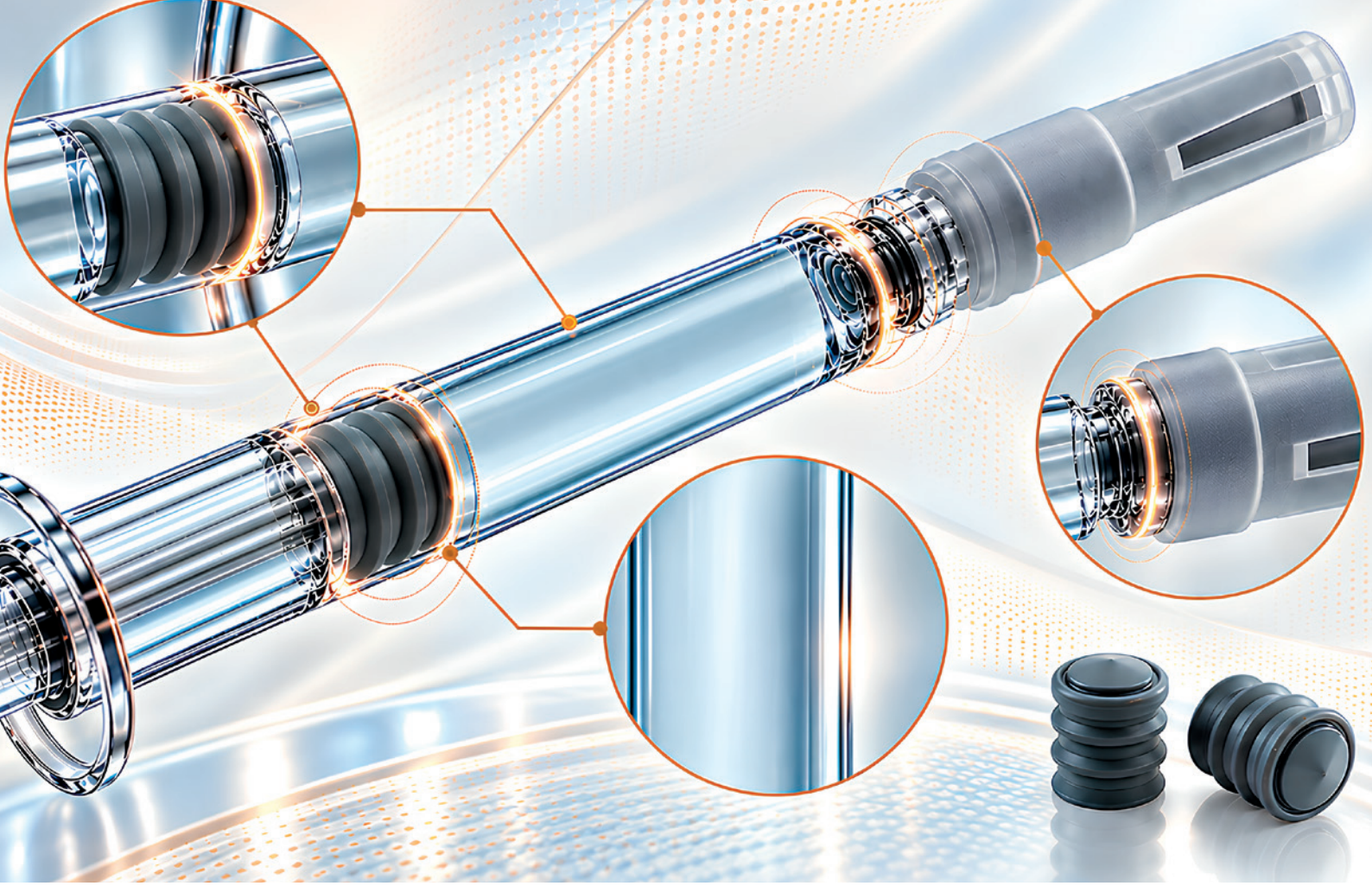
Dr Shirish Ingawale

Shirish Ingawale, MS, PhD, is Director of Device & Combination Product Development at Takeda. He brings more than 20 years of experience in medical devices, drug delivery technologies and combination products across academia and the medical device, biotechnology and pharmaceutical industries. Dr Ingawale leads strategic innovation and cross-functional development to advance patient-centred device and combination product solutions.

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USP <382> SYSTEM-LEVEL INSIGHTS TO SUPPORT EARLIER PACKAGING DECISIONS

Aptar pharma

Drawing on **Aptar Pharma**'s system-level collaboration framework, **Pavan Hemmege Venkatappa**, Technical Product Manager at Aptar Pharma, explains how testing aligned with USP <382> can generate insights that support earlier decisions in packaging and delivery system development and can help development teams better understand system behaviour, identify potential risk areas and guide packaging system decisions before formal validation begins.

USP <382> defines new functional performance requirements for packaging and delivery systems used in injectable drug products, with pharmaceutical companies now responsible for demonstrating compliance at the final assembled-system level. However, beyond regulatory compliance, testing aligned with USP <382> can also generate insights that support earlier decisions in packaging and delivery system development.

FROM COMPLIANCE REQUIREMENT TO EARLY STRATEGIC INSIGHT

For many teams working on injectable products, USP <382> is a regulatory milestone in the development roadmap. The pharmacopoeia chapter addresses the functional suitability of packaging and delivery system components within the assembled system, emphasising overall system performance rather than individual component characteristics.

As a result, this approach moves the discussion away from isolated component behaviour and closer to the way the final system actually performs when all variables come together: components, geometry, liquid properties and manufacturing conditions (Figure 1).

In practice, this broadens the value of the data generated around USP <382> beyond mere compliance. When system-level testing is performed earlier and the resulting data are reviewed with the right questions in mind, it can help teams gain early insights into how a syringe or cartridge

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Figure 1: USP <382> assessment as a development checkpoint.

system behaves under different conditions. This is especially relevant before the final drug product, final configuration or full validation strategy is available.

Such system-level testing and related early learnings can be achieved through close collaboration between component providers. The approach may include testing under standard conditions, with placebo formulations or with representative liquids. These data are not a substitute for final product testing and cannot be used directly as proof of regulatory compliance for a specific drug product. Nevertheless, they can provide useful directional information at a point in development where design teams are still comparing options and trying to understand where the system may be sensitive to variation.

> "WHEN SYSTEM-LEVEL TESTING IS PERFORMED EARLIER AND THE RESULTING DATA ARE REVIEWED WITH THE RIGHT QUESTIONS IN MIND, IT CAN HELP TEAMS GAIN EARLY INSIGHTS INTO HOW A SYRINGE OR CARTRIDGE SYSTEM BEHAVES UNDER DIFFERENT CONDITIONS."

LOOKING AT THE DATA INSIGHTS AS A KNOWLEDGE MAP

USP <382>-oriented preliminary data usually bring together several types of information – primarily from functional tests, such as break-loose force, glide force, leakage and container closure integrity (Figure 2). They may also include environmental conditioning, ageing at different time points, exposure to stress conditions and studies with different viscosities to represent a range of formulation behaviours.

Viewed individually, these results can answer narrow questions. For example, a force value may be assessed against an expected range; a leakage result may pass or fail; or a closure integrity result may support a given interpretation. However, when the same type of testing is available across comparable syringe configurations or material combinations, the data can begin to function as a map of system behaviour.

Each test can be seen as a way of probing the physics of the system. Break-loose and glide/extrusion force results give insights into friction, lubrication and plunger movement. Leakage and container closure integrity results point towards sealing performance and interface behaviour. Ageing and stress conditions help show whether performance remains stable over time or begins to drift. Viscosity studies can reveal how the liquid itself influences the forces required to initiate and maintain movement.

USING USP <382> DATA TO DE-RISK DEVELOPMENT

The value of the data depends largely on how they are used. If the review is limited to checking whether a result is within an expected range, the broader value of the data can be overlooked. A more useful approach is to ask what variables seem to influence the result and which mechanisms may explain the observed results.

Typical variables include barrel and plunger geometry, the interface between components, material properties, siliconisation level and distribution, and liquid properties such as viscosity. The output responses may include break-loose force, glide force profiles, leakage behaviour and sealing performance. By looking across those inputs and responses, teams can begin to identify cause-and-effect relationships.

In this sense, the data create a learning loop – system inputs such as configuration, formulation characteristics and use requirements can be connected to measurable outputs, helping teams refine the questions they ask and focus subsequent development work based on the answers (Figure 3).

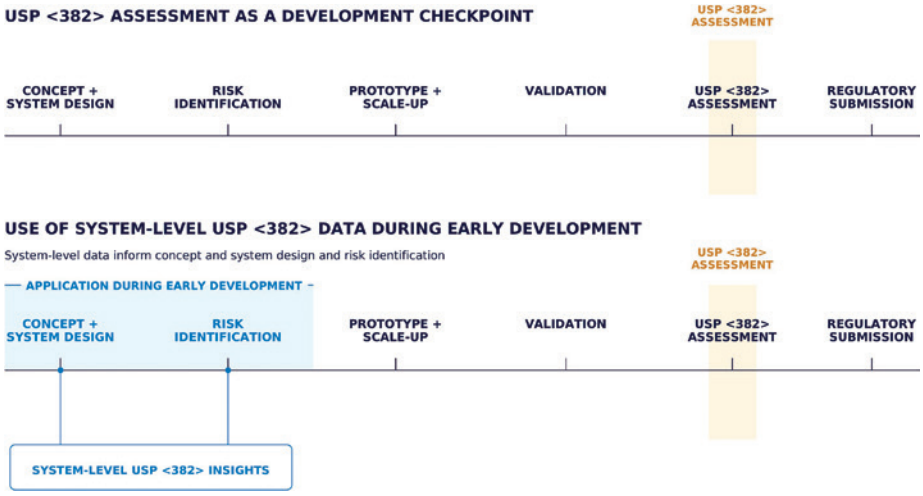


Figure 2: From compliance requirement to early de-risking insight.

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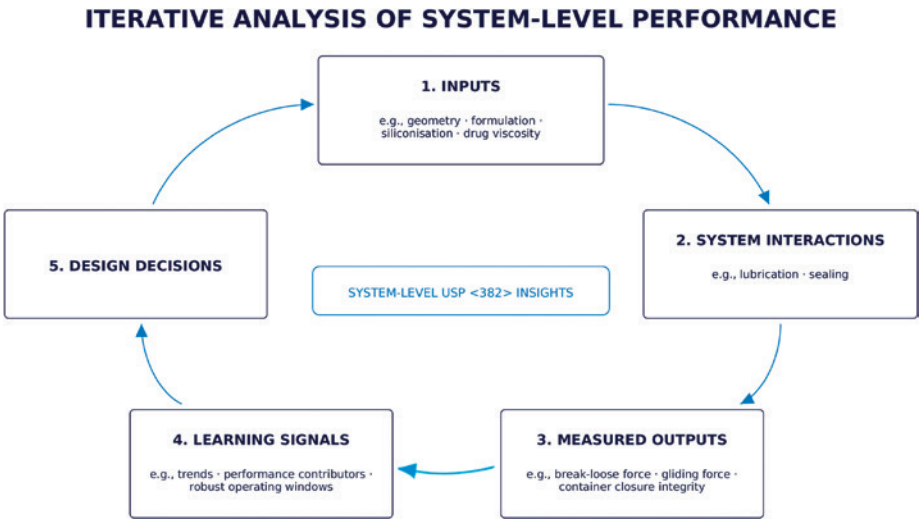


Figure 3: USP <382>-oriented data insights in a learning loop.

> "WHEN DATA ARE GENERATED UNDER COMPARABLE CONDITIONS, IT CAN HELP DEVELOPMENT TEAMS BUILD A PRACTICAL VIEW OF THE DESIGN SPACE."

This learning-loop approach can be valuable during concept selection and early development. By generating evidence on how product, container and device characteristics interact, it can help teams identify potential risks sooner, focus development efforts on the most relevant performance drivers and build confidence in the robustness of the final combination product.

USING COMPARATIVE DATA TO EXPLORE THE DESIGN SPACE

When data are generated under comparable conditions, it can help development teams build a practical view of the design space. They can help identify performance trends across design variants, observe sensitivity to certain parameters and distinguish between configurations that show stable behaviour and those that appear more sensitive to variation.

For example, one configuration may show relatively consistent glide forces across different representative liquids, while another may become more variable as viscosity increases. A sealing interface may remain robust after conditioning in one system but show a narrower operating window in another. While such observations do not remove the need for final testing with the intended drug product, they can help teams identify which systems appear most robust and pinpoint the areas that require particular attention.

By creating a shared basis for discussion between pharmaceutical companies and their device partners, these insights can help teams compare design and component options more systematically, particularly when multiple products or configurations may need to be considered within a broader platform approach.

That distinction can be particularly beneficial before scale-up activities introduce additional variability, before stability studies are launched or before customer-specific configurations are locked. It gives teams an earlier opportunity to discuss risk drivers. These discussions are easier to act on early, rather than after a design has been fixed and the project is moving towards validation.

A PRACTICAL EXAMPLE: READING FORCE PROFILES AS LEARNING SIGNALS

This can be illustrated by an early development team comparing two syringe system configurations for a formulation expected to have higher viscosity than water. At this stage, the team may not yet have the final drug product available for full testing. A representative data package using liquids of different viscosities can provide useful information. If one configuration shows a gradual and predictable increase in glide force as viscosity rises, while another shows more variable behaviour or a less stable force profile, the team has a useful signal. The result does not determine the final choice by itself, but it helps to frame the next questions (Figure 4).

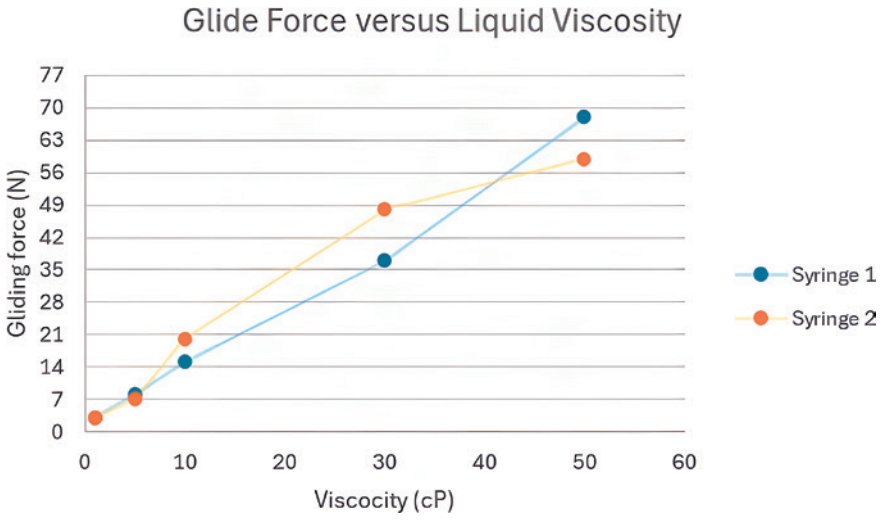


Figure 4: Illustrative glide force response across representative liquid viscosities. Syringe 1 demonstrates a predictable response to increasing viscosity, whereas Syringe 2 shows greater variability. Such trends can provide early insight into system sensitivity and help guide subsequent development activities. Data shown for illustration only.

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Those questions may include whether the observed behaviour is linked to geometry, lubrication, the elastomer interface, liquid properties or a combination of factors. The team can then decide whether to run targeted follow-up tests, adjust a configuration, review the siliconisation strategy or focus attention on a narrower set of risk areas. This is a more efficient way to learn than running broad exploratory tests without a clear hypothesis.

CLARIFYING THE SCOPE AND BOUNDARIES OF EARLY PERFORMANCE DATA

However, there is an important boundary to maintain. Representative data packages are not final evidence of functional suitability for a specific drug product in its final packaging or delivery configuration. Final testing remains necessary, and the final assembler is responsible for demonstrating system performance under the appropriate conditions.

Early data serve a different purpose – they help teams ask better questions sooner; they support technical discussions before formulation assumptions become fixed; and they can reveal where the system behaves consistently and where it may be more sensitive to change. Their value lies in providing additional evidence to support risk assessments, strengthen development justifications and better understand formulation-related performance sensitivities, without replacing final product-specific testing.

"BY COMPARING RESULTS ACROSS DEFINED CONFIGURATIONS, MATERIALS, LIQUID PROPERTIES AND CONDITIONING CONDITIONS, DEVELOPMENT TEAMS CAN BETTER UNDERSTAND HOW THE PACKAGING AND DELIVERY SYSTEM RESPONDS TO CHANGE."

CONCLUSION

USP <382> remains an important compliance milestone, but the data generated around it can also support development much earlier when reviewed as system-level evidence rather than as isolated test outputs.

By comparing results across defined configurations, materials, liquid properties and conditioning conditions, development teams can better understand how the packaging and delivery system responds to change. This can help to identify potential sensitivities, focus technical discussions on the most relevant risk areas and strengthen the rationale behind design decisions while options are still open.

Used in this way, USP <382>-oriented data provide an earlier knowledge base that can make subsequent development more informed, more transparent and better aligned with the objective of defining a robust final packaging system. Through its system-level collaboration with glass manufacturers and pharmaceutical partners, Aptar Pharma supports this earlier use of performance data to help inform packaging decisions before formal compliance activities begin.



Pavan Hemmege Venkatappa

Pavan Hemmege Venkatappa is Technical Product Manager for the Pre-Filled Syringe (PFS) Product Line within Aptar Pharma's Injectables division. He brings more than a decade of product development experience across industries with demanding performance and safety requirements, including automotive safety components and personal protective equipment. In his current role, Mr Hemmege Venkatappa is responsible for new product development, product strategy and lifecycle management for PFS solutions, while working closely with customers on technical requirements and evolving injectable drug delivery needs. He is an engineering graduate of Arts et Métiers ParisTech (France).

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Interview:
Contamination Control in Practice: BD's Global, Risk-Based Approach to Supporting Sterile Drug Manufacturing

In this interview, **Patrick Jeukenne**, President of **BD Pharmaceutical Systems**, and **Frédérique Pedretti-Abel**, Vice-President of Quality, both of **BD**, explain how the company is putting contamination control into practice through global strategy, concrete investments and measurable actions. This approach is designed to support pharmaceutical manufacturers' compliance and operational performance, while ultimately contributing to the quality and safety of medicines delivered to patients.

Q Why has contamination control become such a critical topic for sterile drug manufacturers?

PJ Contamination control has become a central consideration in sterile drug manufacturing. The primary concern is the potential impact of contamination on the quality and safety of medicines and, ultimately, on patients. Beyond this fundamental responsibility, contamination also creates significant operational and compliance challenges for pharmaceutical manufacturers.

"A CONTAMINATION EVENT CAN TRIGGER A CASCADE OF DEVIATIONS AND INVESTIGATIONS, REJECTED BATCHES, LINE STOPPAGES OR SUPPLY DISRUPTIONS, AFFECTING BOTH PERFORMANCE AND CONFIDENCE."

Since the publication of the revised EU GMP Annex 1 on August 25, 2022, and its full implementation on August 25, 2023, the Contamination Control Strategy (CCS) has become central to sterile manufacturing, with pharmaceutical companies increasingly expecting their suppliers to demonstrate robust, risk-based and continuously improving contamination control practices.

The consequences of contamination reach further than many people would assume. Around 30% of injectable drug recalls are linked to foreign-matter contamination.[1] First and foremost, contamination can directly affect the quality and safety of a medicine and, ultimately, the patient receiving it. The impact is also operational. A contamination event can trigger a cascade of deviations and investigations, rejected batches, line stoppages or supply disruptions, affecting both performance and confidence.

The contamination risk also extends across the full value chain. No single actor can control every part of it, which makes it essential for each of us to take responsibility for the risks within our own scope.



Patrick Jeukenne

President of
BD Pharmaceutical Systems

Patrick Jeukenne is Worldwide President of BD Medical Pharmaceutical Systems, a global business of BD focused on advancing innovative drug delivery solutions for the pharmaceutical and biotechnology industries. In this role, he leads a global organisation dedicated to helping customers bring life-changing therapies to patients safely and efficiently around the world. Mr Jeukenne has more than 30 years of experience across the pharmaceutical, biotechnology and medical technology sectors, spanning leadership roles in quality, commercial operations, strategy, business development and general management. Throughout his career, he has been passionate about driving innovation, operational excellence and strong customer partnerships to improve healthcare outcomes. A pharmacist by training, Mr Jeukenne is based in Switzerland.

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Q How has the revised EU GMP Annex 1 changed expectations around contamination control?

FPA Annex 1 marks a key shift for our industry. Contamination control is no longer approached as a collection of separate requirements, but as an integrated strategy across the manufacturing system. Manufacturers are expected to take a holistic, risk-based approach, with controls proportionate to the identified risks and supported by documented rationale.

This approach encompasses the key elements that can influence contamination risk, including people, processes, equipment, materials, environmental monitoring, facilities and utilities. These elements must be considered together within the CCS, which should be reviewed regularly and continuously improved as risks, processes and manufacturing practices evolve.

As a supplier, we are increasingly expected to demonstrate how our own contamination control practices contribute to the overall control of risks across the pharmaceutical value chain. What matters most for the pharmaceutical industry is that responsibility now extends beyond manufacturers' own facility walls, and that can only be addressed collectively through aligned, transparent collaboration.

Q What commitments has BD made to strengthen contamination control across operations?

PJ We know that commitment needs to be visible in the budget and in the targets. Otherwise, it remains only language.

We have set explicit improvement targets that we track and report: a 15% year-on-year reduction in foreign-matter internal deviations, and a 10% year-on-year reduction in contamination complaints. These commitments reflect our responsibility to improve the quality of the components supplied to customers and, ultimately, to contribute to the safety of medicines delivered to patients.

A clear signal of our commitment is investment. BD Pharmaceutical Systems' contamination control investment is planned to increase by a factor of 3.5 between FY26 and FY27. This deliberate step change reflects both the importance of the topic and where we believe industry expectations are heading.



Dr Frédérique Pedretti-Abel

Vice-President of Quality

Frédérique Pedretti-Abel, PhD, is Worldwide Vice-President of Quality Management for Pharmaceutical Systems at BD, a role she has held since February 2025. She joined BD in 2020 and has held several senior quality leadership positions across EMEA and international markets. With more than 25 years of experience in the pharmaceutical and MedTech industries, Dr Pedretti-Abel has led global organisations across Quality, Regulatory, Clinical, Operations, R&D and Programme Management. Prior to BD, she held senior leadership roles at Edwards Lifesciences and Novartis. She holds a PhD in Pharmaceutical Sciences and a Swiss Board Diploma from Swiss Board School.

"BD PHARMACEUTICAL SYSTEMS' CONTAMINATION CONTROL INVESTMENT IS PLANNED TO INCREASE BY A FACTOR OF 3.5 BETWEEN FY26 AND FY27."

Beyond our targets and investment is a strategy that is deployed globally rather than site by site. It combines executive governance, global quality policies and priorities, transversal programmes that cut across functions and locations, and a consistent risk-based approach (Figure 1).

Q How is BD's strategy aligned with the expectations of Annex 1?

FPA Risk management is the backbone of our strategy. Rather than creating a separate internal quality programme and then aligning it afterwards, we used Annex 1 expectations as a foundation for the architecture of our approach.

We have organised the strategy

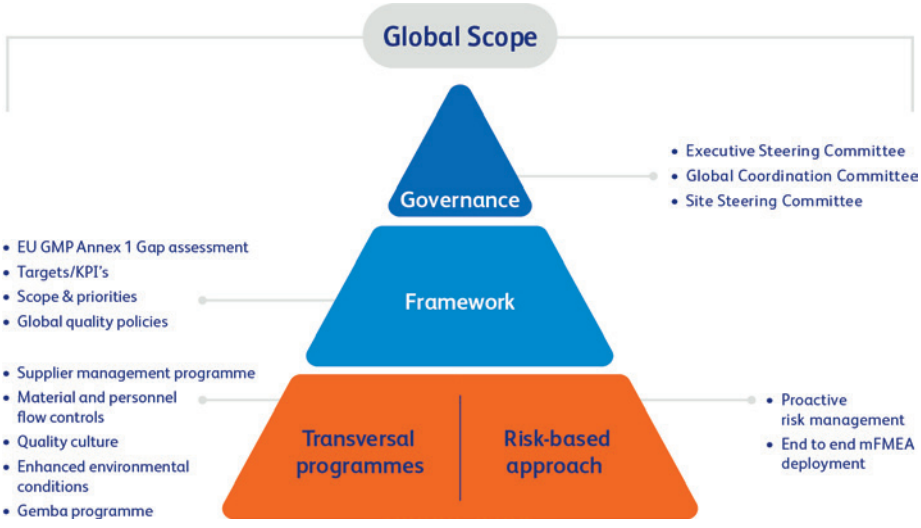


Figure 1: BD global CCS framework.

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Figure 2: The five pillars of BD CCS.

around five pillars (Figure 2). The first two pillars address what BD builds and maintains: environment and monitoring, and equipment, facilities and utilities. The next two pillars focus on how we work: personnel and quality culture, and processes and control. The final pillar extends beyond BD's own walls: suppliers, materials and external services. Together, these areas reflect the operational reality of sterile manufacturing, where contamination prevention depends on many connected decisions.

Within each pillar, we apply the same disciplined risk-management cycle. We identify contamination risks, assess their criticality, focus resources where risk is highest, define and implement mitigation actions, and then track effectiveness. Residual risk and lessons learned are reviewed regularly and fed back into our continuous improvement process.

Q What does seeing contamination control as a mindset mean within BD?

PJ We know that contamination control cannot belong to the quality department alone. If it does, it will eventually fail. Contamination risk is influenced by decisions made every day across the organisation, from operations and engineering to procurement and maintenance. That is why contamination control needs to be a shared responsibility across businesses.

To combat that, we have deliberately positioned contamination prevention as a business priority rather than solely a quality responsibility. With strong leadership endorsement within BD, contamination prevention is embedded into how we manage and discuss business performance.

Over the past 12 months, we have also started sharing our CCS journey more openly with customers. These exchanges are an important part of our approach, allowing us to share our experience, listen to their perspectives and continue learning together.

FPA Building on what Patrick said, this type of mindset only holds if it is supported by consistent practices. Our task is to make the right behaviour the standard behaviour across BD globally.

That starts on the shop floor, with standardised practices across sites. It continues through training and team engagement because people apply standards more reliably when they understand their purpose and believe in the value they create.

One of the foundational tools we use is the Gemba walk. This practice brings leaders and quality teams closer to the people doing the work, helping identify risks, assess controls and drive continuous improvement together. More than 350 Gemba walks were conducted across BD manufacturing sites in 2026. In the end, this is where culture and system come together.

Q How does BD translate its CCS into concrete actions across its manufacturing network?

FPA Our CCS is supported by a multi-year roadmap, with concrete actions already implemented and further improvements being progressively deployed across our manufacturing network. A major initiative is the improvement and standardisation of gowning practices across our global network. This represents a significant investment and a tangible step towards strengthening and standardising contamination prevention practices across our sites. It is complemented by our company-wide awareness campaign, which helps embed contamination prevention into everyday behaviours.

At the same time, we are acting directly on our manufacturing environment and processes. Environmental conditions have already been optimised in high-risk process steps, including selected stopper-loading areas and some Visioguard™ lines, while further upgrades at points of exposure are planned. Risk-based cleaning and disinfection programmes are being implemented, and personnel and material flows are being reviewed to further reduce contamination risks.

Our approach also extends beyond our manufacturing sites. Contamination control expectations have already been reinforced with our top suppliers, with broader deployment planned. In parallel, initiatives such as double-bagging of rubber components and Gemba walks at distribution centres help to address contamination risks across the wider supply chain.

Q How can these upstream actions translate into measurable value for pharmaceutical manufacturers?

FPA The logic of upstream control is straightforward: a contamination risk eliminated at our site is a risk our customer does not need to detect, investigate or absorb.

For customers, more predictable component quality can mean fewer incoming-quality issues, fewer unplanned

"OUR CCS IS SUPPORTED BY A MULTI-YEAR ROADMAP, WITH CONCRETE ACTIONS ALREADY IMPLEMENTED AND FURTHER IMPROVEMENTS BEING PROGRESSIVELY DEPLOYED ACROSS OUR MANUFACTURING NETWORK."

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deviations during production, fewer line interruptions and less product scrap. It can also reduce investigation burden and free quality resources for higher-value work. In addition, relevant documentation can support customers in their own EU GMP Annex 1 assessments and audit-readiness activities.

We have already seen this translate into measurable value in customer-related data. On one dedicated stopper line, implementation of an end-to-end action plan combining risk assessment, enhanced environmental conditions and revised supplier specifications demonstrated a 28% reduction in complaints per million over 18 months.

Q What is the key message you would like pharmaceutical manufacturers to take away?

FPA Annex 1 has made clear that contamination control cannot rely on isolated controls. It requires a connected, risk-based and continuously improving strategy across the supply chain. At BD, we are translating that expectation into concrete actions across our sites, processes and supplier network, with the goal of supporting our customers' quality, compliance and zero-defect mindset.

PJ Our commitment can be summarised in three dimensions. First, accountability: we are responsible for controlling the risks within our part of the value chain and for contributing to trust in every injection. Second, action: we are investing, setting measurable targets and continuously improving our practices to support our customers' zero-defect mindset. Third, impact: by addressing contamination risks upstream, we aim to contribute to more predictable manufacturing performance, stronger supply continuity and, ultimately, the quality and safety of the medicines delivered to patients.

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BD SCF™ PremiumCoat® supports:

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*When compared to 12.7 mm special thin wall (STW) needle
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¥ Gliding test performed at nominal design space, in BD Neopak™ Glass Prefillable Syringe 2,25mL 27G filled with WFI

1. BD Neopak™ 1mlL customer quality specification, Le Pont-de-Claix, France; Becton, Dickinson, 2017 **2.** BD Neopak™ and BD Neopak™ XSi™ 2.25 mL customer quality specifi cation, Le Pont-de-Claix, France; Becton, Dickinson, 2020 **3.** Injection time and ejection force calculation [internal study], Le Pont-de-Claix, France; Becton, Dickinson and Company, 2021 **4.** Depaz et al. Cross-Linked Silicone Coating: A Novel Prefilled Syringe Technology That Reduces Subvisible Particles and Maintains Compatibility with Biologics JOURNAL OF PHARMACEUTICAL SCIENCES 103:1384–1393, 2014 **5.** DVTR20192507_DV data BD SCF™ PremiumCoat® 1 mlL R&D data [internal study]. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2023. **6.** TR20234488 Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024 **7.** BD SCF™ PremiumCoat® Plunger Stopper 1mlL Customer quality specifications. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2022. **8.** BD SCF™ PremiumCoat® Plunger Stopper 1-3mL Customer quality specifications. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2023. **9.** Design Control Evidence BD SCF™ Premiumcoat® 1mlL with integrated biologics system data in Neopak Syringes. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2021 **10.** Design Control Evidence BD SCF™ Premiumcoat® 1-3mL with integrated biologics system data in Neopak Syringes. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024

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Interview:
Eco-Inject: Bringing Affordable Sustainability to Single-Use Disposable Autoinjectors

In this exclusive interview, **Michael Earl** and **Steven Kaufman** of **Eco-Inject** speak with ONdrugDelivery's Guy Furness about the significant progress the company has made throughout 2026 since its highly successful funding round earlier in the year, discussing what's new in the world of Eco-Inject, what sets the device platform apart from other approaches to sustainability in the autoinjector space, and how the industry is reacting to Eco-Inject as it moves towards the market.

Q What's new for Eco-Inject in 2026 and, looking forward, what does the future look like for you?

ME 2026 is a pivotal year for Eco-Inject. The key ideas behind the company and our device have been brewing in the brilliant mind of John Palmer-Felgate for the last few years, and in January of this year, we completed an over-subscribed fundraising round to make it a reality. We're now making steady progress towards finalising the design, definitive regulatory standards testing and putting industrialisation capacity into place to ensure device supply for clinical trials and commercialisation.

SK I think what's new for Eco-Inject this year is the team of people that John has put together; everyone has a strong background in the industry, and that's given us access to some of the best partners, as well as key biotech and pharma companies. The things that make Eco-Inject different have also really started to stand out. We won a Red Dot Award earlier this year and we've now been announced as a finalist for two CPHI Awards (Figure 1) – now, of course, awards are not the be-all and end-all, but they demonstrate that what we're putting forward is resonating and that people are really starting to pay attention.

Of course, there are some great devices out there – some of which Michael and I have been directly involved with – that are doing a terrific job for single-use disposable autoinjectors. But, when you look at Eco-Inject, it stands out from other products on the market. These days, more companies are saying that they want sustainability, but also that they don't want to pay a premium for it. Pharma wants an autoinjector that's cost effective, technically strong and doesn't look like every other device on the market today. That's what we're offering with Eco-Inject.



Figure 1: Eco-Inject won a Red Dot Award earlier this year and is up for further awards at CPHI 2026.

"PHARMA WANTS AN AUTOINJECTOR THAT'S COST EFFECTIVE, TECHNICALLY STRONG AND DOESN'T LOOK LIKE EVERY OTHER DEVICE ON THE MARKET TODAY. THAT'S WHAT WE'RE OFFERING WITH ECO-INJECT."

Q Can you expand on the response you've received from the market since the launch of the Eco-Inject autoinjector?

ME To be clear, we've not yet started doing any major outreach across the industry – we're still primarily focused on getting the product absolutely right. We want to be certain that when we say what we can do, not

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Michael Earl

Chief Commercial Officer

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Michael Earl is a veteran of the life sciences industries, with more than 40 years' experience in both biopharma and medical device companies, as well as in private equity investing. Most recently, he was the Director of the Pharma Services business for Owen Mumford, and immediately before that was the Commercial Vice-President for Bespak. He has extensive experience in the development and commercialisation of drugs, devices and combination products. He currently serves as the Chief Commercial Officer for Eco-Inject alongside consulting for companies and investors in these fields.



Steven Kaufman

Chief Strategy Officer

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Steven Kaufman is a distinguished executive in the drug delivery industry with more than 21 years of experience delivering innovative solutions to pharmaceutical and biotechnology companies. He is the Executive Director of Combination Product Solutions, as well as serving as Portal Instruments' Chief Commercial Officer and Eco-Inject's Chief Strategy Officer, bringing extensive expertise in combination products and self-injection technologies. Before setting up Combination Product Solutions in January 2023, Mr Kaufman held executive leadership positions in strategy, marketing and business development at several industry-recognised organisations, including Stevanato Group, Bespak and SHL Medical.

only do we know we can do it, but that we've got the data to back it up. That being said, we've already spoken to a significant cross-section of the industry, all the way from big pharma looking for future pipeline platforms to regional players that have significant positions in niche markets, and we're finding that our device is really resonating. We're in an encouraging position.

Steven and I have been involved in the drug delivery device space for a long time now, so we know where the friction points are when you're trying to introduce something new to the market; if you think back 20 or 25 years to when the current market leaders were designed, nobody in their wildest dreams thought they'd be being manufactured in the volumes that they are today. It's a similar thing with sustainability – we were talking about it back in the 2000s, but nothing like the degree to which we are now.

We have ensured that our design fits in with what the industry currently expects. Our device sticks to the classic two-step, single-use disposable autoinjector formula that millions of patients across the world are used to and expect. That way, there's less friction for pharma companies and it also makes life easier from a regulatory perspective.

SK The market has changed a lot recently with the advent of glucagon-like peptide-1s (GLP-1s) and the great success they've seen. I think this shift can only be an advantage for us, with more patients better educated about using autoinjectors and pen injectors in general because either they or someone they know uses one. We're now seeing the second and third waves of variations on GLP-1s and, as we get into the 2030s, we're going to start seeing generics and biosimilars reaching the market, some of which could potentially be in an Eco-Inject autoinjector.

Q How would you describe the difference between Eco-Inject and other approaches to sustainable autoinjectors?

ME Put simply, it's a combination of three things – our device is sustainable, single-use and affordable. There are biopolymers that could replicate current autoinjector designs, but if you want them to have the same structural properties as the oil-based polymers currently in use, it will be expensive. And while everybody wants to be green, nobody wants to pay for it. So, having something that's of a similar cost to current options and fits in with established manufacturing methods is important.

John was able to achieve this by essentially starting from a blank sheet of paper. He started from the fact that used autoinjectors are biohazard waste and need to be incinerated at end-of-life. By burning oil-derived polymers, you're adding to the carbon in the atmosphere by releasing carbon that was previously locked up in fossil fuels. Using a plant-based polymer means that you can follow exactly the same disposal path as current devices, creating a sustainable device platform for which nobody has to change their behaviour. To do it with biopolymers that are available at a reasonable cost, you have to design around the structural properties of those polymers.

What John has done with Eco-Inject is to design the device so that the strain of holding the spring under tension is largely taken by stamped metal parts, which massively opens up the materials design space to biopolymers that wouldn't be able to handle that strain on their own.

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The metal from autoinjectors is routinely recovered during incineration anyway, so by using polymers where the carbon in them was captured from the atmosphere in the first place, you're getting a dramatic decrease in the carbon footprint. We're currently finalising the lifecycle analysis, and we're excited about sharing the numbers – they're impressive.

Q Could you tell us more about how you're handling testing and manufacturing?

ME Before I moved over to devices, I was in pharma and biopharma for decades, so I know from experience that they do not want to add any more risk into drug product development programmes than is absolutely necessary. With that in mind, we've made sure that all the testing equipment we've got both in-house and that we use with our partners all meets industry standards (Figure 2). For example, we've got Instron (Norwood, MA, US) equipment installed in our facility for testing Eco-Inject with ISO-standard 1 mL long and 2.25 mL prefilled syringes and so far we've had no issues with any of them (Figure 3).

John and his engineering support are close to finalising the commissioning of the assembly equipment as well. The equipment is all designed in-house, but uses all of the standard processes and components you'd see with any of the mainstream manufacturers. It's a means of demonstrating that Eco-Inject has been designed so that it can be manufactured at very high speed, in very high volumes. We've already run a short experiment with it running at about 60 pieces per minute, which is ridiculous for the footprint of the manufacturing machine that we've got at the moment. We're not expecting to get into the manufacturing equipment business; what we're doing is showing that we can use standard assembly approaches and that Eco-Inject will fit right in with established processes.



Figure 2: In-house testing for Eco-Inject.



Figure 3: Eco-Inject is designed to work with both 1 mL long and 2.25 mL syringes within a single device.

Q Can you tell us more about the thinking behind the branding and the form factor of the device?

SK My MBA studies were in Marketing and International Business, so I love good branding. All our executives were actively involved in this process at the beginning of the year. We recently put in the work and investment to do a rebrand because we wanted not only the logo of the company but also the image to resonate with the industry, and you're starting to see that come through in all our branding and materials. At the heart of it, it's about making sure that our core messages are well-maintained – the sustainability aspect of Eco-Inject and everything else that comes with that.

Back from when I started in the industry, it surprised me that sample devices weren't sent in proper packaging with proper labelling. It was a different world 20 years ago. Pharma and biotech companies are quite an experienced group, and they expect to see platform devices that can support them right away for clinical trials with minimal investment up front. A lot of companies now are saying they'd like to be clinic-ready in six to eight months. That used to be 12 to 18 months. We're keeping that in mind so that we know exactly what the market expects, and hopefully our branding and our messaging are on point and give people a better understanding of what Eco-Inject stands for and what the executives are trying to put forward.

Q Are you able to give us any insight into the types of conversations that you're currently having with the industry?

ME It's a real cross-section. On the one hand, we're talking with big pharma companies that are looking for a platform for their pipeline products that are coming through. As I'm sure your readers will know, for most big pharma companies, the majority of the

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products coming through are injectable, so we've seen a lot of interest there.

Alongside them we have a significant number of biosimilar companies who are looking to start semaglutide biosimilar programmes, for example. However, these companies are looking at the market and recognising that it's significantly different to most other biosimilar markets because it's so big, and that scale brings both sustainability problems and cost challenges. So we're very well positioned there with a product that tackles both those issues.

SK We've even got some big pharma and biotech companies looking at Eco-Inject and asking if there's scope to adopt it as an internal platform. Most of those companies are already with the top echelon of autoinjector platform suppliers and they're looking at Eco-Inject for a potential second-generation product, with the aim of boosting sustainability across multiple products. We've also been in conversations with small- and mid-sized companies that have a good product and a good pipeline, but they're finding that they also need to present a very clear overview of their sustainability position for some of their tenders. And I think what's pivotal to our success here is that, while it's good to have sustainability as an offering, it's great to have it paired with a clever design and proper intellectual property protection.

"I THINK WHAT'S PIVOTAL TO OUR SUCCESS HERE IS THAT, WHILE IT'S GOOD TO HAVE SUSTAINABILITY AS AN OFFERING, IT'S GREAT TO HAVE IT PAIRED WITH A CLEVER DESIGN AND PROPER INTELLECTUAL PROPERTY PROTECTION."

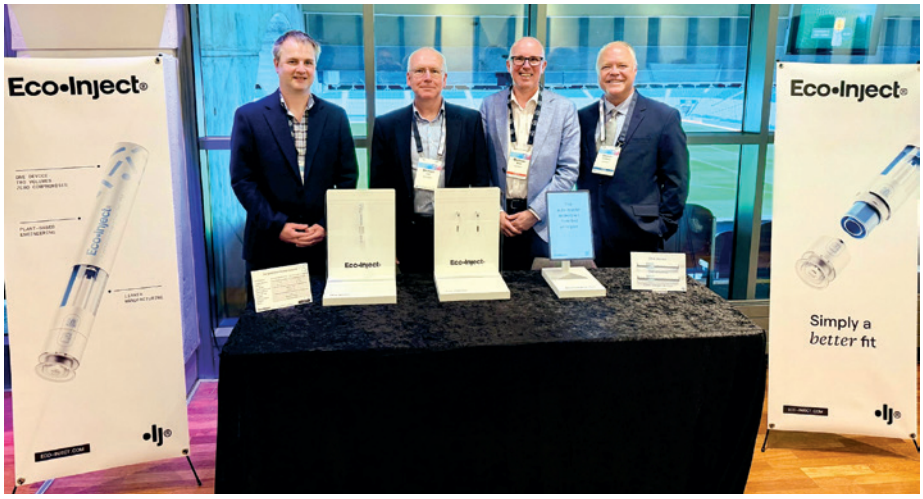


Figure 4: The Eco-Inject team looks forward to meeting colleagues throughout the upcoming 2026–2027 conference season.

Q To close us out, if people want to meet with you during the upcoming conference season, where can they expect to find you?

ME We're aiming to be at all the major events through to the start of 2027 (Figure 4). So, at the start of October, Steven and John will be in Palm Springs (CA, US) for PDA Universe, while Matt White, our Chief Executive Officer, and I will be in Milan (Italy) for CPHI. I'm also going to be at PODD in Boston (MA, US) at the end of October. Steven will be there as well. Then the whole team will be back together in Paris (France) for Pharmapack at the start of next year. Outside of conferences, we welcome people to contact either of us directly. We're reasonably well known throughout the industry, and of course there's our contact page on the Eco-Inject website. We're looking forward to a very productive remainder of 2026 and hope to see many new and familiar faces over the coming months.

SK Our goals for the rest of the year are straightforward. We will lock in production with our contract manufacturing partners to establish work cells that provide installed capacity in the millions, supported by our sub- and final-assembly equipment. We will work with partners such as Instron, Cormica (London, UK) and Gessnet (El Dorado Hills, CA, US) to ensure that our testing, quality and regulatory systems are at the expected level. And, perhaps most importantly, we will be providing sample devices this year as well as running feasibility studies with the target of getting into clinical trials in 2027 with our biotech and pharma partners.

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BUILDING CONFIDENCE IN COMBINATION PRODUCT DEVELOPMENT THROUGH PRE-VERIFIED SYRINGE-DEVICE CONFIGURATIONS

Chiara Carraro and **Enrico Barichello** of **Stevanato Group**, explain how pre-verified autoinjector and prefilled syringe configurations can help pharmaceutical companies make faster, evidence-based decisions when developing combination products for complex injectable therapies.

THE PREFILLED SYRINGE: A PERFORMANCE-CRITICAL COMPONENT

As more injectable therapies move towards self-administration,[1] pharmaceutical companies are under increasing pressure to ensure that drug formulations, primary containers and delivery devices work together reliably from development through commercial launch. The challenge is particularly acute for biologics and other complex injectable products, where high concentrations, high viscosities, large-dose volumes and sensitivity to container materials can all influence device performance.[2] In this context, the prefilled syringe (PFS) is a performance-critical component of the delivery system.

These pressures to ensure reliability are changing the way companies think about container and device selection. A decision made late or based on limited compatibility evidence can lead to avoidable risks: unexpected injection times during stability studies, additional verification work, delays to device integration or even the need to revisit the container choice. Conversely, early access to data on proven

> "A DECISION MADE LATE OR BASED ON LIMITED COMPATIBILITY EVIDENCE CAN LEAD TO AVOIDABLE RISKS."

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syringe-device configurations can give development teams a clearer understanding of expected behaviour and help to mitigate technical and functional risks associated with combination product development.

FROM COMPATIBILITY TESTING TO DEVELOPMENT DE-RISKING

Compatibility testing is often referred to as a confirmation step, but its strategic value is much broader. When performed early and systematically, it can help to reduce uncertainty around the interaction between the components of a combination product.

Stevanato Group's approach is to generate data around pre-verified configurations. Rather than asking customers to start from an entirely blank page, these data packages provide an evidence base for selecting and implementing a suitable configuration. This can be particularly valuable when teams need to understand formulation behaviour over time, meet shelf-life expectations and maintain a positive patient experience – all within a compressed development timeline.

If consistent device behaviour is observed, teams can gain confidence in performance trends earlier rather than waiting until the end of shelf life. In this way, lower variability in initial tests may help to optimise development activities and support faster decision-making.

AIDAPTUS® AND STEVANATO GROUP PFSs: PRE-VERIFIED CONFIGURATIONS

Aidaptus is a two-step, single-use autoinjector platform with a highly adaptable device architecture (Figure 1). Developed through an integrated collaboration model between Owen Mumford (Chipping Norton, UK) and Stevanato Group, and combining device, syringe, manufacturing and supply-chain expertise, the platform is designed to accommodate both 1 and 2.25 mL PFSs within the same form factor. Additionally, its plunger rod technology automatically adjusts to the fill volume, supporting flexible filling without changing device parts. The platform enables configuration choices for different formulation and delivery requirements and is available with low- and high-drive spring options – making it suitable for a range of viscosities.

Figure 1: Aidaptus autoinjector platform.



Within Stevanato Group's syringe portfolio, Nexa® and Alba® offer different performance profiles for demanding injectable applications (Figure 2). Nexa glass syringes, featuring an optimised silicone level, are designed for biologics and offer tight dimensional tolerances, high cosmetic quality, consistent functionality and compatibility with multiple drug delivery devices.

Alba syringes are intended for next-generation biologics and formulations sensitive to silicone oil. Their internally cross-linked silicone coating is designed to deliver near-zero levels of silicone oil-related subvisible particles and reduce silicone migration along the barrel, supporting consistent gliding performance over time. Alba syringes do not require dedicated or ad-hoc plungers and can be used with commercially available ISO-standard plungers, providing greater flexibility in plunger selection.



Figure 2: 2.25 mL Nexa and Alba syringes.

"THE VALUE OF COMBINING AIDAPTUS WITH STEVANATO GROUP'S PFSs IS NOT LIMITED TO COMPONENT COMPATIBILITY. IT FITS INTO A WIDER INTEGRATED OFFERING."

The value of combining Aidaptus with Stevanato Group's PFSs is not limited to component compatibility. It fits into a wider integrated offering: primary containers, delivery systems, final assembly knowledge and analytical testing, which can be co-ordinated within a single ecosystem. For customers, this reduces the number of interfaces to manage and helps to align container, device and testing decisions.

STUDY DESIGN: EVALUATING DELIVERY PERFORMANCE OVER REAL-TIME AGEING

Stevanato Group conducted a stability study to assess the injection-time performance of 2.25 mL Nexa and Alba syringes when assembled with the Aidaptus autoinjector sub-assemblies incorporating a low-drive spring.

The syringes were prefilled with a 1 cP biotech placebo solution and stored under real-time ageing conditions of 25°C and 60% relative humidity. The study evaluated performance at 0, 3, 6 and 12 months. Thirty samples per syringe category were used for each time point.

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Delivery time was measured using a high-speed camera; after activation of the autoinjector, the camera recorded the interval from needle deployment to the end of liquid delivery (Figure 3). This provided a gauge of how the syringe and autoinjector performed together after ageing.

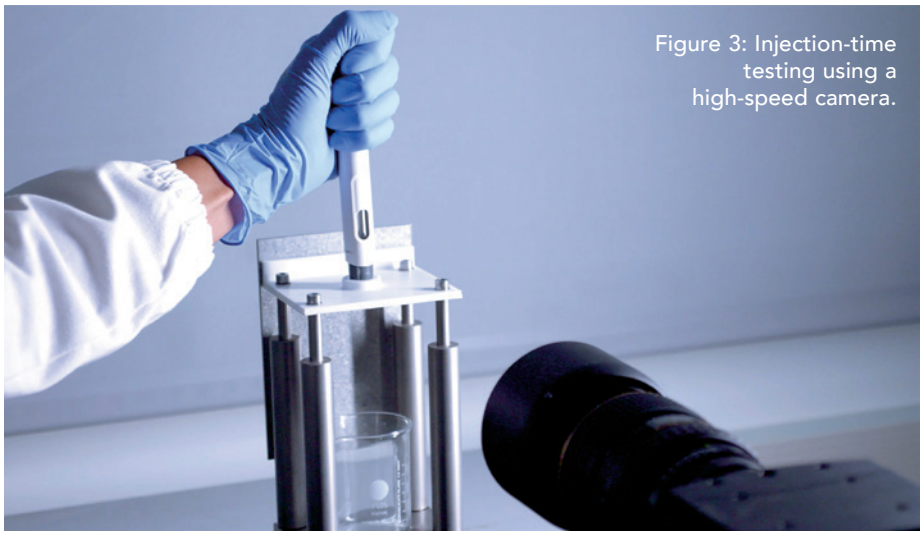


Figure 3: Injection-time testing using a high-speed camera.

WHY REPRESENTATIVE PLACEBO MODELS MATTER

For compatibility testing to be meaningful, the test model must reflect the stresses that a real formulation may place on the syringe and device system. Water for injection can be useful during early evaluations, but it does not necessarily challenge the container closure system in the same way as a biologic formulation would. Excipients and surfactants, such as polysorbate 80, can interact with siliconised surfaces and may influence break-loose force, gliding and injection time.[3]

In the stability study, Stevanato Group used a representative test formulation rather than water for injection. The aim was to create a more demanding and realistic model for observing delivery performance over time. This approach also illustrates a wider service capability – Stevanato Group's Technology Excellence Centers can develop ad hoc models and test configurations that mimic customer formulation behaviour, helping customers to obtain predictive data before committing to later-stage verification activities.

WHY INJECTION TIME MATTERS

Injection time is a practical and patient-relevant indicator of combination product performance. In a spring-driven autoinjector, the available driving force is fixed, as determined by the device configuration. This means that, if the frictional behaviour of the syringe changes over time because of formulation-container interactions, silicone redistribution or changes in break-loose and glide forces, the time required to deliver the dose may also change.

From a patient perspective, excessively long or variable injection times may affect confidence, comfort and the likelihood that the full dose is delivered as intended. ISO 11608-1, which describes needle-based injection systems for medical use, stresses that, "the time or speed employed to deliver a discrete volume would be based upon tolerability or convenience".[4]

From a development perspective, a consistent injection-time profile can give teams confidence that the selected syringe-device configuration is behaving predictably when ageing. This is why delivery-time testing, alongside other functional and physical assessments, can play an important role in de-risking combination product development.

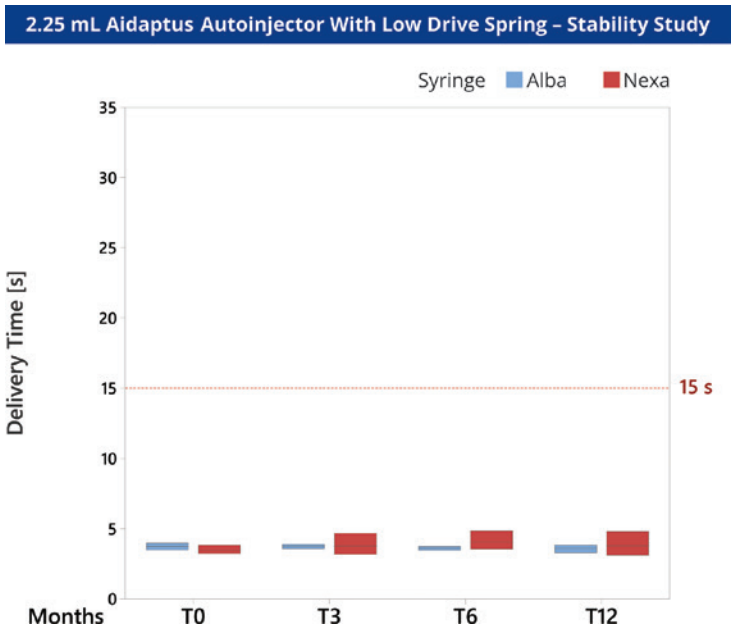


Figure 4: The stability study assessed and compared how injection time changed after 3, 6 and 12 months with Nexa and Alba PFSs assembled in the Aidaptus autoinjector. Both Alba and Nexa maintained delivery times well below 15 seconds throughout the evaluated ageing period.

STUDY RESULTS: CONSISTENT DELIVERY TIMES

Both Nexa and Alba syringe configurations worked effectively with the Aidaptus autoinjector under the study conditions. Both categories maintained successful delivery performance across all tested ageing conditions (Figure 4). Differences in injection-time behaviour reflected the distinct design and platform characteristics of the two syringe technologies, providing customers with options

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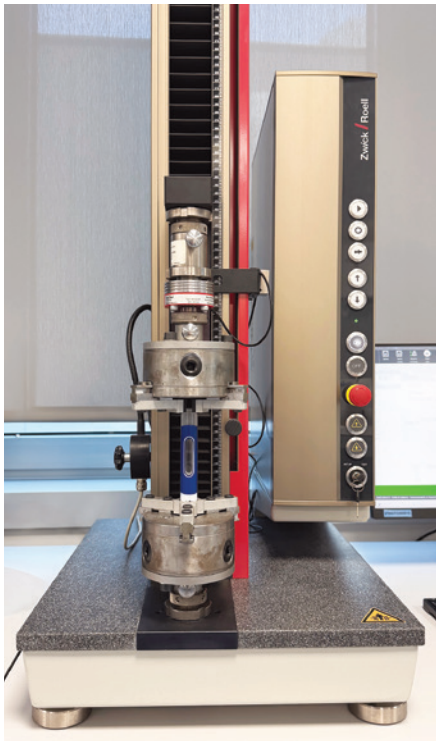


Figure 5: Cap removal force testing.

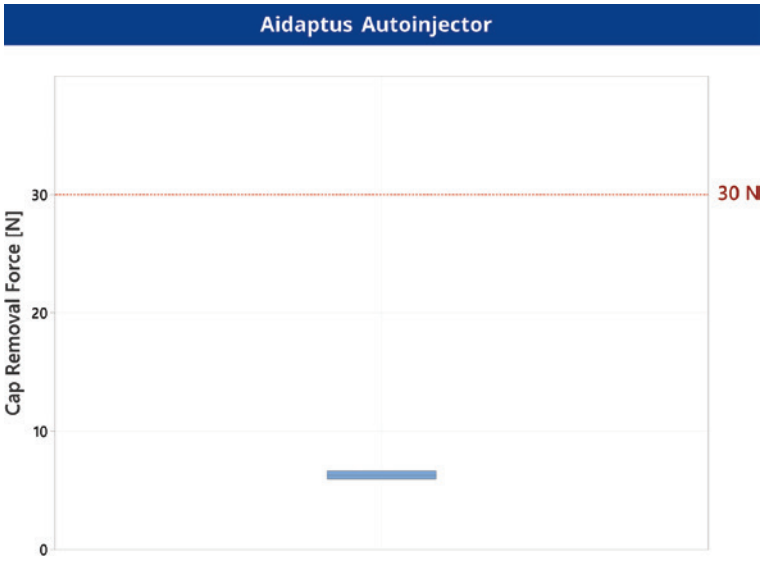


Figure 6: Graph representing cap removal force for Aidaptus autoinjector. No additional effort was required to remove the cap from the syringe, illustrated by the highly consistent results.

depending on their formulation and drug requirements. Under the evaluated conditions, Alba exhibited lower variability in injection time over ageing.

In addition to injection-time performance, the compatibility assessment considered other functional parameters relevant to user handling and dose delivery. Cap removal force testing demonstrated that no additional effort was required to remove the cap (Figure 5) compared with controls. The observed cap-removal forces remained consistently low and well below the 30 N acceptance threshold (Figure 6), supporting ease of cap removal while maintaining the intended container closure integrity.

Dose-accuracy testing demonstrated that the combination of Aidaptus and either PFS configuration consistently delivered the intended target dose of 2.1 mL (Figure 7). The delivered volumes measured for the high- and low-spring variants were essentially equivalent, indicating reliable dose delivery performance. Under the evaluated conditions, both spring configurationsaccurately delivered the intended target dose.

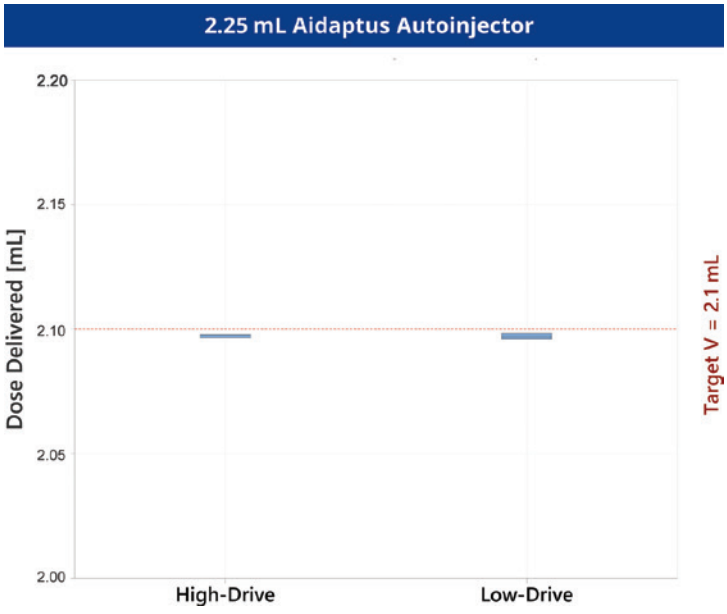


Figure 7: Graph of dose accuracy at high- and low-drive spring configurations. The dose-accuracy test established that the combination of Aidaptus and either PFS, Alba or Nexa, can accurately deliver the intended dose.

TURNING EARLY EVIDENCE INTO A DEVELOPMENT ADVANTAGE

With the attention of pharmaceutical teams pulled in multiple directions during the development of a drug-device combination product, the study demonstrates how a device partner can ease some of this burden. Easier decision-making at the device selection stage gives pharmaceutical

"EASIER DECISION-MAKING AT THE DEVICE SELECTION STAGE GIVES PHARMACEUTICAL TEAMS GREATER SCOPE TO FOCUS RESOURCES ON THEIR CORE PRIORITIES."

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teams greater scope to focus resources on their core priorities, whether that be drug development, manufacturing strategy, clinical supply or commercialisation planning.

As injectable therapies continue to evolve, understanding the interactions between the primary container and delivery device is critical to avoid complications at later, more demanding stages of development. The compatibility study between Aidaptus and Nexa and Alba PFSs provides one example of how early data can provide a foundation for more confident device selection. Ultimately, the benefit is not simply a compatible syringe and autoinjector combination, but greater confidence in the path to commercial launch.

For further information on the evaluation and tested configurations, please contact Stevanato Group.

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MAKE SYRINGE–DEVICE DECISIONS WITH GREATER CONFIDENCE.

For complex injectable therapies, container and device choices can influence delivery performance, injection time and development risk. Stevanato Group brings syringe, device and testing expertise together to help teams make earlier, evidence-based decisions through pre-verified syringe-device configurations and move forward with greater confidence.

Read the article in this issue.





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Technology Showcase

MASTERING PRODUCT TRANSFER FOR A RANGE OF INJECTABLES

For injectable drug products, quality is often associated with formulation development and final filling operations. However, an equally critical phase occurs between these stages – product transfer. The movement of a product from one processing step to the next can have a significant impact on consistency, uniformity and overall product integrity. As formulations become more complex, transfer operations must be designed to accommodate a wide range of physical and processing characteristics while maintaining product quality throughout manufacturing.

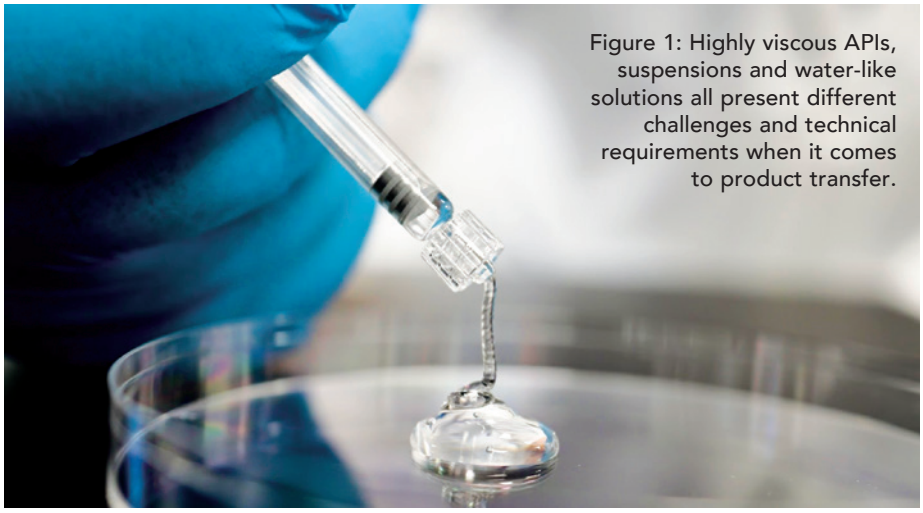


Figure 1: Highly viscous APIs, suspensions and water-like solutions all present different challenges and technical requirements when it comes to product transfer.

THE HIDDEN COMPLEXITY OF PRODUCT TRANSFER

Different formulations can place very different demands on manufacturing systems. Fully understanding those demands is critical for success. A transfer strategy that works effectively for a water-like solution may not be suitable for a highly viscous product or a suspension prone to rapid settling (Figure 1). As a result, transfer technologies must be carefully aligned with product-specific requirements. The ultimate objective is to maintain molecular fidelity while delivering the product consistently and efficiently throughout the manufacturing process.

> "A TRANSFER STRATEGY THAT WORKS EFFECTIVELY FOR A WATER-LIKE SOLUTION MAY NOT BE SUITABLE FOR A HIGHLY VISCOUS PRODUCT OR A SUSPENSION PRONE TO RAPID SETTLING. AS A RESULT, TRANSFER TECHNOLOGIES MUST BE CAREFULLY ALIGNED WITH PRODUCT-SPECIFIC REQUIREMENTS."

A TOOLBOX FOR DIVERSE PRODUCT CHALLENGES

A variety of transfer approaches can be employed depending on the characteristics of the product in question (Table 1). Peristaltic pumping technologies are commonly used for standard solutions, transferring products to a surge vessel before gravity feeding them to downstream operations. Sterile applied nitrogen may also be incorporated as part of the transfer process. For products requiring greater force, positive displacement technologies can provide an effective solution for both sterile and non-sterile applications. Extremely viscous products may require piston-driven transfer systems that use piston-and-cylinder technology.

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Product Type or Challenge	Transfer Solution
Standard solutions	Peristaltic pumping with surge vessel and gravity feed
Oxygen-sensitive formulations	Sterile applied nitrogen
Applications requiring controlled movement	Positive displacement systems
Extremely viscous products	Piston-and-cylinder technology
Formulation-specific challenges	Custom transfer solutions

Table 1: Product transfer technology overview.

Suspension Behaviour	Product Transfer Strategy
Settling occurs over hours	Continuous mixing within the vessel
Settling occurs within minutes	Recirculation loop extending towards downstream processing equipment
Product concentration variability is a concern	Active suspension management strategy

Table 2: Suspension management approaches.

KEEPING SUSPENSIONS UNIFORM FROM START TO FINISH

Suspension-based products introduce another level of complexity to transfer operations. Unlike true solutions, suspensions can change over time as particles settle, creating the potential for product variability during manufacturing. Continuous mixing and recirculation strategies can help to maintain product homogeneity throughout processing (Table 2).

THE ROLE OF MIXING AND RECIRCULATION

For suspensions that remain stable for several hours before settling, continuous mixing within the vessel can help maintain product homogeneity. Products that settle within minutes may require recirculation systems extending towards downstream processing equipment to maintain homogeneity.

"UNLIKE TRUE SOLUTIONS, SUSPENSIONS CAN CHANGE OVER TIME AS PARTICLES SETTLE, CREATING THE POTENTIAL FOR PRODUCT VARIABILITY DURING MANUFACTURING."

DESIGNING TRANSFER PROCESSES AROUND PRODUCT COMPLEXITY

Process developers understand that there is no universal solution for product transfer. The success of a transfer depends on selecting the appropriate combination of transfer technologies, mixing capabilities and recirculation strategies to address the specific characteristics of each formulation.

DOWNSTREAM CHALLENGES BEYOND PRODUCT TRANSFER

While product transfer lays the foundation for successful product handling, it represents only the first step in the overall manufacturing journey. Downstream filling operations introduce the next set of challenges, particularly for complex or sensitive products. Considerations such as oxygen, lighting and bubble control, temperature management, plunger-position accuracy, shear sensitivity and the management of highly viscous formulations become increasingly important when developing a robust end-to-end product handling and filling process that maintains product quality through to final container closure.

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Expert View

GETTING OUT OF A JAM: SUSPENSION DELIVERY, OCCLUSION AND DEVICE DESIGN

Dr Alex Vasiev of Sanner Group discusses suspension-based parenteral systems, including micro- and nanoparticle suspensions and colloidal dispersions, where sedimentation, mechanical bridging and interfacial forces can strongly influence delivery performance.

"LONG-ACTING INJECTABLE TECHNOLOGIES CAN EXTEND DOSING INTERVALS FROM DAYS TO WEEKS OR MONTHS, REDUCING TREATMENT BURDEN, CLINIC VISITS AND ADHERENCE CHALLENGES."

SUSPENSIONS AND PARTICULATE FORMULATIONS IN DRUG DELIVERY

Suspensions and particulate formulations are an important area of innovation in drug development and delivery.[1] They are used across multiple routes of administration, including inhalation, oral, ophthalmic, nasal and parenteral delivery.[2]

Their value lies in enabling the administration of compounds or payloads that are difficult to stabilise or deliver as conventional solutions. Particle morphology, chemistry and solid-state form can be engineered to modify dissolution, improve stability, protect labile payloads, control biodistribution or alter pharmacokinetics. For proteins and monoclonal antibodies (mAbs), particulate, crystalline and matrix-based approaches are also being investigated to address high-concentration formulation challenges, reduce injection volume, eliminate certain solvents and mitigate aggregation or degradation risks.[3]

Long-acting injectable technologies can extend dosing intervals from days to weeks or months, reducing treatment burden, clinic visits and adherence challenges. These technologies include implants, injectable depots, drug-eluting devices and suspension-based formulations.[4]

Commercial adoption of long-acting injectables is well established in psychiatry, particularly for long-acting antipsychotic depots used for schizophrenia treatment, where poor adherence to daily oral therapy is associated with relapse, hospitalisation and poorer long-term outcomes. In 2022, Okoli *et al* reported that long-acting injectable antipsychotics may improve outcomes compared with oral antipsychotics, including adherence, relapse, rehospitalisation and symptom-related measures.[5]

"AS WELL AS PSYCHIATRY AND INFECTIOUS DISEASE, LONG-ACTING INJECTABLE AND DEPOT FORMULATIONS ARE ESTABLISHED IN ENDOCRINOLOGY, ONCOLOGY AND METABOLIC DISEASE."

A similar rationale is emerging in HIV therapy and prevention, where long-acting injectable antiretroviral products based on cabotegravir and rilpivirine nanosuspensions have reduced reliance on daily oral dosing. Survey data suggest strong patient interest in injectable nanoformulated antiretroviral therapies, particularly for monthly dosing.[6] Cabotegravir and rilpivirine have also been described as long-acting injectable nanosuspensions designed to enable dosing intervals beyond once-monthly usage.[7]

As well as psychiatry and infectious disease, long-acting injectable and depot formulations are established in endocrinology, oncology and metabolic disease, including peptide and hormone-based depots, such as leuprolide, octreotide and exenatide formulations (Table 1).[8] Interest is also expanding in immunology and biologics, driven by the need for less frequent dosing, improved stability and better deliverability of high-concentration

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Product	Owner/Developer	Drug	Therapeutic field	Route
Abilify Asimtufii	Otsuka Pharmaceutical (Tokyo, Japan)	Aripiprazole	Psychiatry	IM
Abilify Maintena	Otsuka Pharmaceutical (Tokyo, Japan)	Aripiprazole	Psychiatry	IM
Abraxane	Bristol Myers Squibb	Paclitaxel (protein bound)	Oncology	IV
Apretude	Viiv Healthcare (London, UK)	Cabotegravir	Infectious disease	IM
Aristada	Alkermes (Dublin, Ireland)	Aripiprazole lauroxil	Psychiatry	IM
Aristada Initio	Alkermes (Dublin, Ireland)	Aripiprazole lauroxil	Psychiatry	IM
Brixadi	Camurus (Lund, Sweden)	Buprenorphine	CNS/addiction	SC
Bydureon	AstraZeneca	Exenatide	Metabolic disease	SC
Bydureon BCise	AstraZeneca	Exenatide	Metabolic disease	SC
Cabenuva	Viiv Healthcare (London, UK)	Cabotegravir + rilpivirine	Infectious disease	IM
Depo-Medrol	Pfizer	Methylprednisolone acetate	Rheumatology	IM or IA
Depo-Provera CI	Pfizer	Medroxyprogesterone acetate	Women's health	IM
Depo-SubQ Provera	Pfizer	Medroxyprogesterone acetate	Women's health	SC
Erzofri	Luye Pharma Group (Hong Kong, China)	Paliperidone palmitate	Psychiatry	IM
Fyarro	AADI Biosciences (Morristown, NJ, US)	Sirolimus (protein bound)	Oncology	IV
Invega Hafyera	Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine)	Paliperidone palmitate	Psychiatry	IM
Invega Sustenna	Janssen Pharmaceuticals	Paliperidone palmitate	Psychiatry	IM
Invega Trinza	Janssen Pharmaceuticals	Paliperidone palmitate	Psychiatry	IM
Kenalog	Bristol Myers Squibb	Triamcinolone acetonide	Rheumatology, orthopaedics	IM or IA
Lupron Depot	AbbVie	Leuprolide acetate	Oncology, endocrinology, reproductive health	IM
Lutrate Depot	GP Pharm (Barcelona, Spain)	Leuprolide acetate	Oncology	IM
Okedi	ROVI (Bromley, UK)	Risperidone	Psychiatry	IM
Rekambys	Janssen Pharmaceuticals	Rilpivirine	Infectious disease	IM
Risperdal Consta	Janssen Pharmaceuticals	Risperidone	Psychiatry	IM
Rykindo	Luye Pharma Group (Hong Kong, China)	Risperidone	Psychiatry	IM
Sandostatin LAR Depot	Novartis	Octreotide acetate	Endocrinology	IM
Signifor LAR	Novartis	Pasireotide	Endocrinology	IM
Skytrofa	Ascendis Pharma (Hellerup, Denmark)	Lonapegsomatropin	Endocrinology	SC
Trelstar	Verity Pharmaceuticals (Mississauga, Canada)	Triptorelin pamoate	Oncology	IM
Triptodur	Azurity Pharmaceuticals (Woburn, MA, US)	Triptorelin	Endocrinology	IM
Uzedy	Teva Pharmaceuticals (Tel Aviv, Israel); MedinCell (Montpellier, France)	Risperidone	Psychiatry	SC
Vivitrol	Alkermes (Dublin, Ireland)	Naltrexone	CNS/addiction	IM
Vocabria injection	Viiv Healthcare (London, UK)	Cabotegravir	Infectious disease	IM
Zilretta	Pacira Biosciences (Brisbane, CA, US)	Triamcinolone acetonide	Orthopaedics	IA
Zyprexa Relprevv	Eli Lilly	Olanzapine pamoate	Psychiatry	IM

Table 1: Overview of parenteral suspensions and depot delivery systems. IM: intramuscular; IV: intravenous; SC: subcutaneous; IA: intra-articular.

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products. However, particulate, crystalline and suspension-based approaches for mAbs and larger biologics remain at comparatively early stages, with much of the work still focused on formulation development, preclinical evaluation or translational studies.[3]

CHALLENGES IN DELIVERING SUSPENSIONS

A well-designed suspension must balance physical stability with usability. It should remain sufficiently uniform to permit accurate dosing, avoid forming hard cakes during storage and redisperse readily before use.[2] In practice, suspensions may sediment, aggregate or adhere to container surfaces. Many products therefore require shaking, reconstitution or other preparation steps before administration. Even when these steps are followed, rapid sedimentation can alter the dispersed volume fraction during injection and affect dose uniformity. Complete and reproducible resuspension is therefore a critical part of dose preparation and presents a challenge for both the user and the device.

Injection performance is governed by both formulation properties and device geometry. Volume fraction, particle-size distribution, viscosity, particle rigidity, particle shape and particle-particle or particle-container interactions can all alter flow behaviour during administration. These variables may contribute to force spikes, inconsistent delivery profiles, surface adhesion, partial or complete occlusion and failure to deliver the intended dose.

"COMPLETE AND REPRODUCIBLE RESUSPENSION IS THEREFORE A CRITICAL PART OF DOSE PREPARATION AND PRESENTS A CHALLENGE FOR BOTH THE USER AND THE DEVICE."

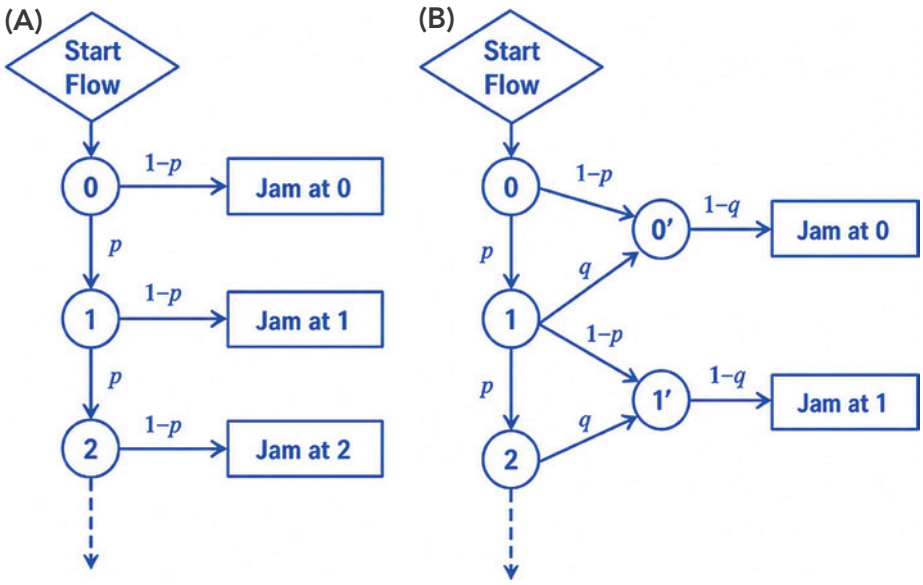


Figure 1: Illustration of flowing and blocked states for reversible and permanent occlusion events. (A) A linear sequence of flow states, (B) an intermediate reversible blocked state.

Weak and Strong Jams

When a suspension is delivered through a needle, cannula or catheter, the flow path may transition between flowing, weakly jammed and permanently blocked states. For device development, it is useful to distinguish between reversible events – which may clear under additional pressure, vibration, shear or changes in flow – and permanent events. These events are often stochastic, where identical injections can produce different outcomes (Figure 1). In a single-step breakdown model, the probability of reaching permanent occlusion

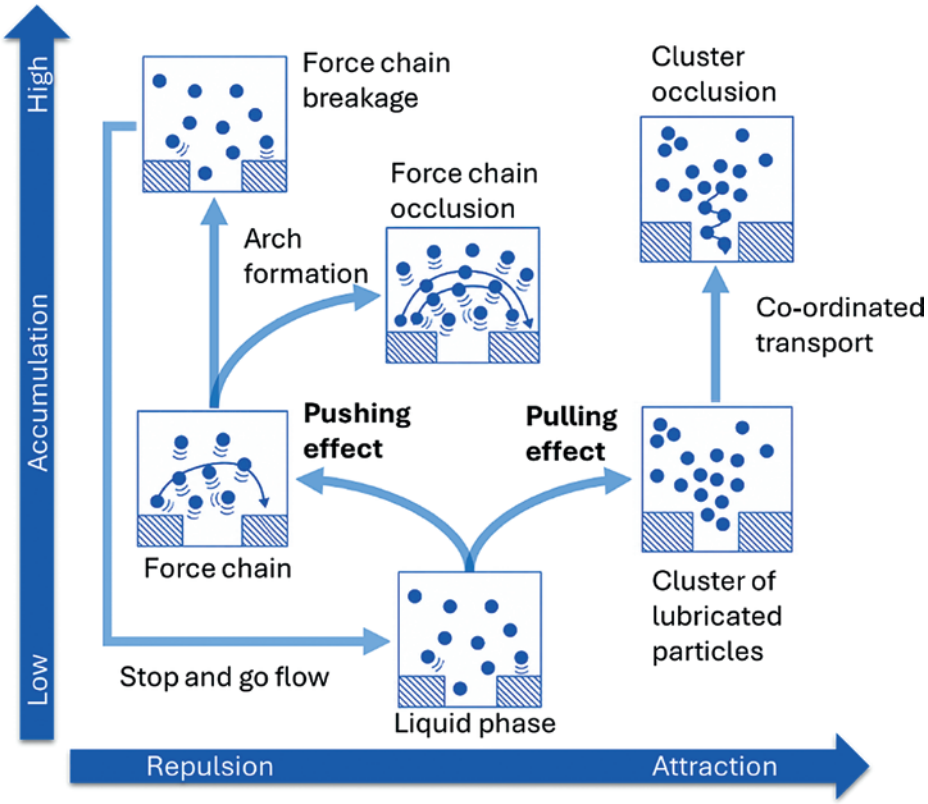


Figure 2: Occlusion mechanisms for different particle interactions.

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at a particular step (n) in the flow is:

$$p^n(1-p)$$

Depending on the nature of the particles and device, an intermediate reversible blocked state may occur. In this case, the system may first enter a weakly jammed state with probability $1-p$, or progress to permanent occlusion with probability $1-q$. The probability of occlusion at step n is therefore:

$$p^n(1-p)(1-q)$$

Although simplified, this probabilistic framing provides a useful way to separate transient events and force spikes from genuine delivery failure.

Occlusion Mechanisms

Having established that multiple factors can contribute to jam formation, and that these may lead to either reversible or permanent occlusion, the next step is to identify the parameters most useful for prediction.

Micro- and nanoparticle suspensions can exhibit a mechanical jamming behaviour when the particle concentration or volume fraction become sufficiently high. As suspensions flow through a constricted path, particles compete for space and may form mechanically stable arches through the development of force chains between neighbouring particles (Figure 2). The dominant occlusion mechanism depends strongly on particle-particle interactions, particularly whether attractive interactions are present. Simulations with dense suspension flow have also demonstrated discontinuous shear thickening and thinning behaviour at high shear rates.[9]

Weak jams are typically stabilised by tangential frictional forces and may be disrupted by vibration, transient pressure fluctuations or local shear, often described in terms of fragility.[2,3] This distinction is important from a device-development perspective because weak jams can often be mitigated or reversed through delivery system design.

Beyond particle concentration, the constriction ratio (C) is one of the most important predictors of mechanical jamming:

$$C = D/d$$

where D is the flow path or inlet diameter and d is the particle diameter. As this ratio decreases, the probability of blockage increases, particularly as the constriction ratio falls below approximately four, although the exact threshold depends on the system geometry, interparticle interactions and flow conditions under consideration.[3–5]

This mechanism is particularly relevant for larger microparticles, embolic beads and cell therapies. In these systems, occlusion can be usefully described in terms of the number of particle escapes through the constriction before a stable jam forms, providing a practical measure of occlusion probability and delivery robustness. This concept becomes especially useful when considering probabilistic models of blockage and delivery performance.

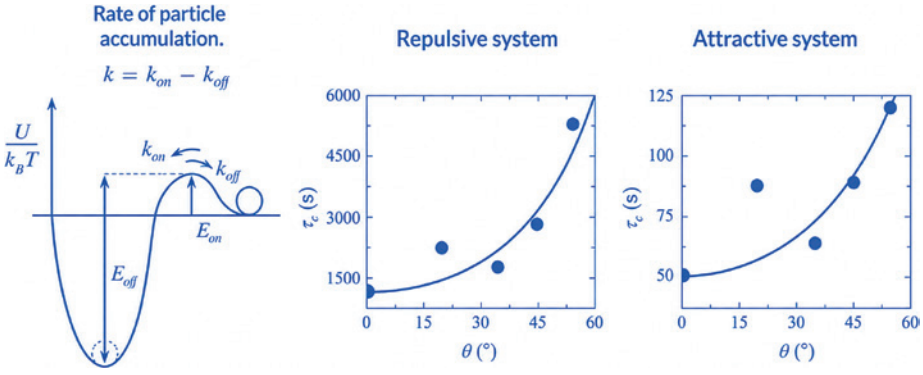


Figure 3: Energy barriers for adsorption and separation, and resulting characteristic clogging time τ^c as a function of wall angle for repulsive and attractive particle systems. Reproduced from Van de Laar *et al.*[11]

Surface Chemistry, Aggregation and Adhesion

Colloidal and nanoscale suspensions are generally too small to bridge a constriction mechanically, meaning occlusion is more likely to arise through particle-particle aggregation, particle-wall adhesion or gradual surface deposition. The extended Derjaguin–Landau–Verwey–Overbeek (DLVO) theory is commonly used to describe the tendency of suspended particles to aggregate or adhere to surfaces.[10] The total interaction energy between a particle, fluid and surface can be expressed as:

$$G^{total} = G^{el} + G^{AB} + G^{LW}$$

where G^{el} is the electrostatic double-layer interaction, G^{LW} is the Lifshitz–van der Waals interaction, and G^{AB} is the acid-base interaction term associated with polar, hydrophobic and hydrogen-bonding effects.

Formulation and surface chemistry are therefore major determinants of delivery performance. Hydrophobicity is especially relevant in pharmaceutical delivery systems because many syringe lubricants, such as silicone oil, and several primary-container materials, including cyclo-olefin co-polymers and cyclo-olefin polymers, are themselves hydrophobic. Valsesia *et al* demonstrated that hydrophobic interactions can significantly increase nanoparticle adsorption onto hydrophobic surfaces by lowering the energy barrier for particle-surface contact (Figure 3).[10] In practice, hydrophobic particles may therefore adhere more readily to hydrophobic polymers and may also exhibit increased particle-particle aggregation, a well-recognised phenomenon of suspension formulations.

Although suspension surface energetics are largely established during formulation development, the implication for delivery-device design is clear: systems not developed with suspensions in mind may not provide reliable performance. Adhesion risk should therefore be assessed holistically using representative formulations, contact materials and flow geometries.

Formulations that maintain strong electrostatic or steric repulsion are generally

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less likely to accumulate at surfaces, whereas attractive particle-particle or particle-wall interactions can accelerate deposition and occlusion. These adhesion-mediated processes also introduce a strong dependence on local geometry and interaction potential, forming the basis of the transition-state clogging framework discussed next.

Characteristic Clogging Time

For dilute colloidal suspensions, clogging can be described using a transition-state framework in which particles progressively accumulate until a stable occlusion forms. Van de Laar *et al* investigated this mechanism using a microfluidic model containing repeated constrictions with defined entrance angles.[11] As the particles were much smaller than the channel dimensions, clogging was driven by adhesion-mediated accumulation rather than granular arch formation. The resulting characteristic clogging time can be described by:

$$\tau^c = \tau_0 \, exp[-F_v \delta \, cos(\theta) / (k^B T)]$$

Where:

- τ^c: The characteristic clogging time
- τ_0: The characteristic agglomeration time in the absence of flow enhancement
- F_v: The viscous force acting on the particle
- δ: The activation length associated with the interaction potential
- θ: The wall or pore-entrance angle defined by the local geometry
- k^B: Boltzmann's constant
- T: The absolute temperature.

In this model, particle attachment is treated as a thermally activated process in which a particle must first overcome an energy barrier before adhesion can occur. Flow modifies the aggregation rate because a particle near an inclined wall experiences viscous forces with both normal and tangential components. The normal component promotes attachment, while the tangential component promotes shear-driven removal. As a result, relatively small changes in wall geometry, flow velocity, viscosity, interaction potential or temperature can produce large changes in the characteristic time to occlusion. This also has implications for human factors and use conditions, particularly for therapies administered directly from cold storage.

"RELATIVELY SMALL CHANGES IN WALL GEOMETRY, FLOW VELOCITY, VISCOSITY, INTERACTION POTENTIAL OR TEMPERATURE CAN PRODUCE LARGE CHANGES IN THE CHARACTERISTIC TIME TO OCCLUSION."

The transition-state framework is most relevant for colloidal and nanoscale suspensions where occlusion develops progressively through particle-wall adhesion, aggregation and surface deposition. However, the particle-escape-number model, clogging-volume measurements and characteristic clogging-time approach all provide related stochastic measures of delivery robustness. The escape-number framework is more naturally associated with mechanical arch formation in concentrated dispersions containing larger particles, whereas the transition-state model is more applicable when adhesion-mediated accumulation dominates.

Figure 4 illustrates this experimentally through measurements of delivered volume prior to occlusion for different fully resuspended microparticle formulations dispensed through a range of needle geometries, including a proprietary design in column J. The wide variation in delivered volume highlights the stochastic nature of clogging and demonstrates how relatively small changes in formulation or geometry can substantially alter delivery robustness. Some combinations exhibit rapid and repeatable occlusion, while others maintain flow for large-volume delivery without blocking.

Measuring particle escapes, delivered volume before blockage or characteristic time-to-occlusion provides a practical basis for comparing formulation-device combinations under representative conditions. These measurements capture the stochastic nature of clogging and allow experimentally observed blocking behaviour to be expressed as a probability distribution rather than a single pass/fail outcome.

Figure 5 illustrates how measured blocking-volume data can be converted into a probabilistic prediction of delivery performance. The data are first fitted with an appropriate probability distribution, such as a truncated normal distribution. This distribution is then converted into a cumulative distribution function and inverted, allowing uniformly distributed random numbers to be transformed into sampled blocking volumes using inverse

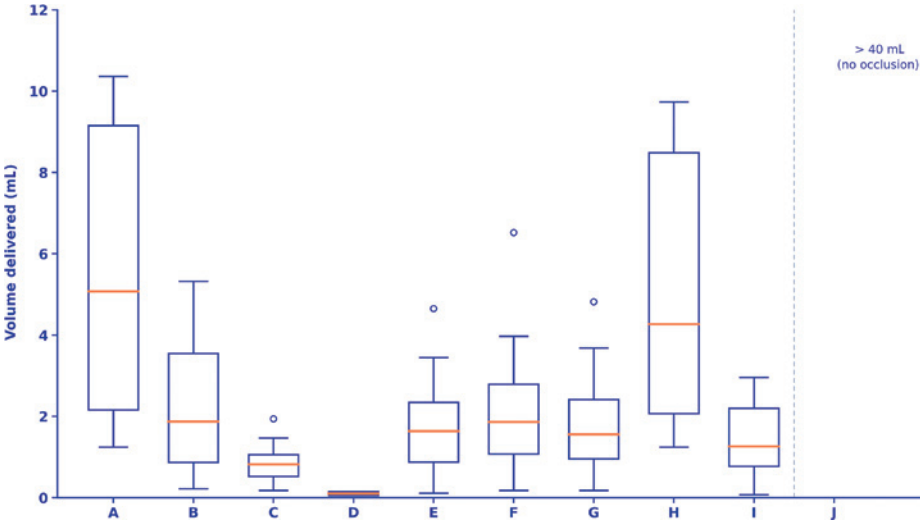


Figure 4: Example measurements of flow until a block occurs for different fully resuspended microparticle formulations dispensed through different needle geometries, including an experimental design (J) developed through mathematical and statistical modelling based on previous test data.

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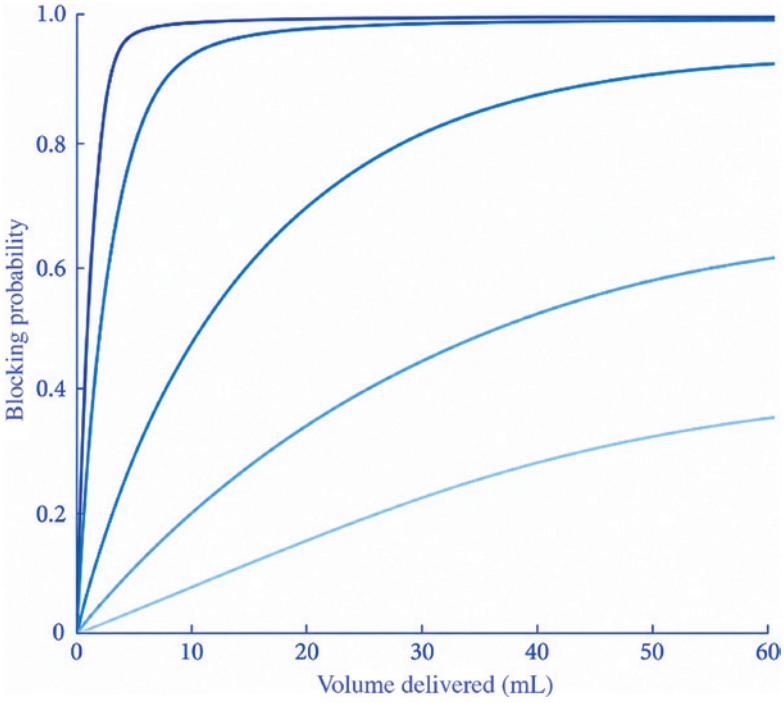


Figure 5: Graph of the blocking probability against volume delivered for different configurations of a delivery system obtained through inverse sampling and Monte Carlo simulation of limited experimental data.

transform sampling. Each sampled value represents one possible blocking outcome from the experimentally observed distribution.

By repeating this process many times, a Monte Carlo simulation generates a population of simulated delivery events, without wasting expensive drug product. The proportion of simulations that undergo a blockage before the target dose is delivered provides an estimate of the blocking probability for that formulation-device combination. Weak or reversible blocks can also be included as conditional events, where a second random number is used to determine whether a blockage clears or becomes permanent based on the experimentally measured probability of weak blocking.

This approach allows experimental data, mechanistic understanding and device-design variables to be combined into a single framework. With appropriate scaling based on measured behaviour, the model can be used to explore changes in formulation, geometry, concentration or flow conditions beyond the specific cases tested experimentally. The result is a practical tool for comparing design options and developing more robust drug-device combinations.

"FOR SUSPENSION-BASED THERAPIES, THE CHALLENGE IS NOT SIMPLY TO DETERMINE WHETHER A FORMULATION CAN PASS THROUGH A NEEDLE, BUT TO UNDERSTAND THE FACTORS THAT INFLUENCE OCCLUSION RISK UNDER REAL-USE CONDITIONS."

CONCLUSION

For suspension-based therapies, the challenge is not simply to determine whether a formulation can pass through a needle, but to understand the factors that influence occlusion risk under real-use conditions. The application of fundamental science, representative testing, human factors insight and probabilistic modelling can help to characterise the formulation-device interactions most likely to drive delivery failure. This understanding can then be carried forwards from early concept development through device design, verification and commercial-scale manufacturing.



Dr Alex Vasiev

Alex Vasiev, PhD, Head of Drug-Device Integration at Sanner, is a multidisciplinary engineer with extensive R&D experience in both academia and consultancy. His primary focus is on the intersection of engineering, physics and biological systems. Before joining Springboard, Dr Vasiev managed front-end design and development at Oval (now SMC). In the field of drug delivery, Dr Vasiev has developed a range of innovations, including smart hydrogel microcarriers, patch pumps, soft mist inhalers and several high-viscosity autoinjectors. He holds an MEng in Mechanical Engineering with Aeronautics and a PhD in Biomedical Engineering from the University of Glasgow (UK).

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BREAKTHROUGH FOR LARGE-VOLUME MANUAL INJECTION: A FIRST-OF-ITS-KIND LARGE-VOLUME PFS IN A PASSIVE SAFETY SYSTEM

Isabelle Jeangoudoux of **SCHOTT Pharma** and **Léa Salfati** of **Nemera** introduce the industry's first fully integrated large-volume passive safety system, combining the syriQ BioPure® 5.5 mL prefillable glass syringe with the Safe'n'Sound® 5.5 mL passive safety system. The authors explain how joint development, compatibility testing and human factors research are de-risking large-volume subcutaneous self-injection at home.

Subcutaneous (SC) drug delivery continues to expand as an alternative to intravenous infusion, supporting the broader shift towards decentralised, patient-centric care. This shift is accompanied by a growing focus on large-volume biologics, with an increasing number of therapies requiring dose volumes beyond the 1–2.25 mL range historically associated with prefillable syringes (PFSs). To meet this need safely and conveniently at home, SCHOTT Pharma and Nemera have worked together to design the first large-volume passive safety system supporting manual self-injection at home: Nemera's Safe'n'Sound® 5.5 mL passive safety system built specifically around SCHOTT Pharma's syriQ BioPure® 5.5 mL staked-needle glass PFS – the first large-volume staked-needle glass PFS on the market.

The syriQ BioPure 5.5 mL PFS was the first-of-its-kind to be verified for at-home use with an autoinjector. There was an unmet need, however, for a 5.5 mL PFS combined with a passive safety system for manual injection. Manual injection devices may be preferred by some users because they retain the familiarity and simplicity of a PFS. Manual injections can also provide greater

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control over the injection experience, including injection speed and visual confirmation of dose delivery. Furthermore, manual devices can be more economical to produce due to the lower complexity of the subassembly, which may be important for some patient groups and geographic regions. Pharmaceutical companies may choose to launch a formulation in both an autoinjector and a manual injection device to cover a broader range of markets.

Requirements for the Safe'n'Sound 5.5 mL system were shaped through direct dialogue with pharmaceutical customers, and the development builds on the established platform compatibility already proven between SCHOTT Pharma and Nemera with 1 and 2.25 mL formats. The result is a large-volume drug delivery solution that offers flexibility of grip posture and strong commercial attractiveness – capabilities that current large-volume delivery options on the market cannot fully match – while making at-home self-injection of biologics accessible to a much larger pipeline of drug formulations. To support this development, SCHOTT Pharma and Nemera have run a structured programme of mechanical, performance and human factors testing.

BUILDING ON AN ESTABLISHED PFS SYSTEM: THE syriQ BioPure 5.5 mL

The syriQ BioPure 5.5 mL is SCHOTT Pharma's first large-volume, staked-needle PFS, extending the proven syriQ BioPure platform beyond its established 1 mL long and 2.25 mL formats (Figure 1). The glass barrel is manufactured from Type I FIOLAX® Borosilicate Glass, engineered for controlled hydrolytic resistance and produced using SCHOTT Pharma's converting process for ultra-low residual tungsten.

First-class components and materials have been chosen for the design of syriQ BioPure 5.5 mL to provide a low extractables and leachables profile that is fit for purpose for sensitive biologics. A high-quality 27G 0.5" special thin-wall needle, with an increased inner diameter relative to a standard 27G thin-wall needle, reduces extrusion force and improves flow performance for more viscous



Figure 1: The syriQ BioPure range from SCHOTT Pharma (1 mL long, 2.25 mL and now 5.5 mL) built on a single, proven glass syringe platform.

formulations. The syriQ BioPure 5.5 mL is also available with a 25G needle variant to broaden the design space and support highly viscous drugs.

For fill-finish partners, syriQ BioPure 5.5 mL is packaged in SCHOTT Pharma's standardised SCHOTT iQ® 3" tub (42 units per tub), the same secondary packaging format used across all three syriQ BioPure volumes, simplifying integration into existing filling lines. The syriQ BioPure 5.5 mL features a shorter, wider syringe geometry that reduces plunger rod length, supporting improved ergonomics, easier device integration and more comfortable handling for patients during self-administration.

INTRODUCING THE NEMERA SAFE'N'SOUND 5.5 mL

Safe'n'Sound 5.5 mL is a single-dose passive safety system intended to handle volumes up to 5.5 mL for SC injection. The safety device is designed to ensure complete dose delivery while protecting users from accidental needlestick injury after injection. The intended patient population spans children to adults, with intended users comprising patients, caregivers and healthcare professionals.

The device user interface comprises four key elements: the rigid needle shield (RNS), the syringe body, the plunger rod and the extended finger flange, sized for the 5.5 mL format (Figure 2). In use, the patient removes the RNS to expose the needle, inserts the needle at a 45°–90° angle, firmly and steadily pushes the plunger rod down until the syringe body is empty and then releases the plunger rod. This activates the spring-driven safety system, retracting the needle automatically into the body system and shielding it from further contact.

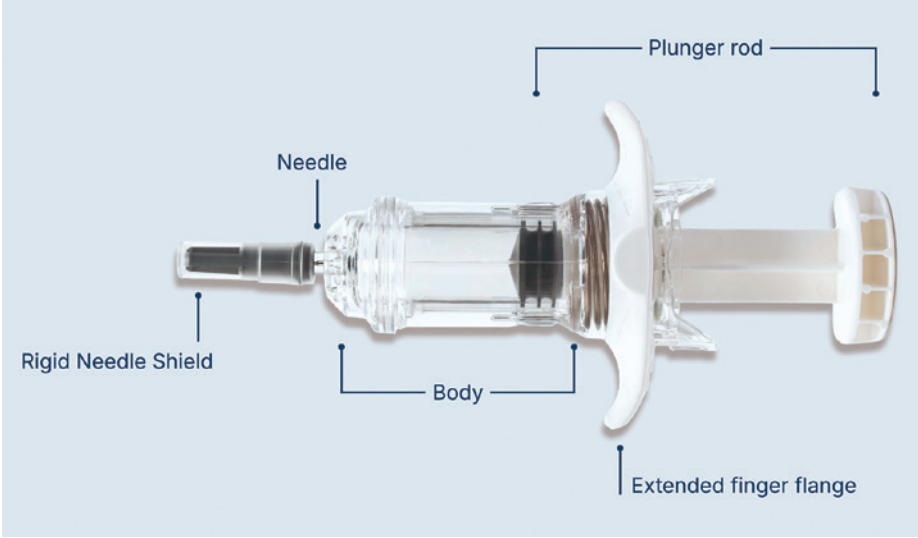


Figure 2: Safe'n'Sound 5.5 mL, showing the rigid needle shield, syringe body, plunger rod and extended finger flange.

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Figure 3: Nemera's Safe'n'Sound range – a proven passive safety system designed to support evolving drug delivery needs (1, 2.25 and now 5.5 mL).

"DESIGNED FROM THE OUTSET AS AN INTEGRATED SYSTEM AROUND THE SYRIQ BIOPURE 5.5 mL STAKED-NEEDLE GLASS PFS, THE DEVICE AVOIDS THE LIMITATIONS OF RETROFIT APPROACHES AND ENSURES FULL COMPATIBILITY BY DESIGN."

A DEVELOPMENT PARTNERSHIP BUILT FOR LARGE VOLUME

SCHOTT Pharma, a pioneer in drug containment and delivery solutions, and Nemera, a global leader in drug delivery devices, have combined their respective expertise to bring the first fully integrated large-volume passive safety system to market. Three principles underpinned the collaboration:

- First fully integrated 5.5 mL passive safety system designed specifically for large-volume SC self-injection
- Seamless compatibility between SCHOTT Pharma's syriQ BioPure glass PFS and Nemera's Safe'n'Sound passive safety device, enabling smoother clinical and commercial development
- A joint system approach that reduces integration risk and accelerates time-to-market for large-volume and biologic therapies.

AN INTEGRATED SYSTEM FOR LARGE-VOLUME THERAPIES

While Nemera's passive safety system platform is already established at 1 and 2.25 mL, Safe'n'Sound 5.5 mL is the first passive safety device specifically engineered for large-volume SC injection with a glass PFS (Figure 3). Developed jointly by Nemera and SCHOTT Pharma, it combines Nemera's capabilities in drug delivery devices with SCHOTT Pharma's expertise in primary packaging. Designed from the outset as an integrated system around the syriQ BioPure 5.5 mL staked-needle glass PFS, the device avoids the limitations of retrofit approaches and ensures full compatibility by design.

Function	Verification Category	PFS Only	PFS + Passive Safety System
Syringe flange breakage	Dimensional & mechanical fit	✓	
PFS assembly into device			✓
Force to unload the syringe			✓
Plunger rod pull-out force			✓
Free fall – before use	Functional performance		✓
Free fall – after use			✓
RNS pull-off force		✓	
Break-loose extrusion force		✓	
Gliding force		✓	
Manual safety system activation			✓
Residual volume			✓
Override of safety system once activated			✓
Needle access distance after use			✓

Table 1: Functional performance and safety features that guide the compatibility assessment of the large-volume safety system.

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Figure 4: The joint SCHOTT Pharma–Nemera compatibility testing framework, from dimensional fit through functional performance to human factors usability.

DE-RISKING LARGE-VOLUME MANUAL SELF-INJECTION THROUGH COMPATIBILITY

Table 1 summarises the key functional and safety attributes considered during compatibility assessments of the large-volume safety system. By distinguishing syringe-specific performance from attributes governed by the syringe and safety system combination, this framework enables a targeted risk assessment and highlights where compatibility has already been verified through integrated system testing.

In a joint verification process, compatibility between the syringe and device was verified functionally as well as dimensionally. Testing for syriQ BioPure 5.5 mL and Safe'n'Sound 5.5 mL followed a three-tier framework spanning dimensional and mechanical fit, functional performance and human factors usability (Figure 4).

Dimensional and Mechanical Fit

Nemera mapped the critical dimensions of the syriQ BioPure 5.5 mL syringe against the safety device interface, defining the tolerances required for reliable engagement and consistent activation (Figure 5).

Functional Performance

A crucial aspect of functional performance of the syringe in manual use is RNS pull-off force. Additionally, for prefilled syringes, break-loose extrusion force over shelf life is key. Glide-force performance of the plunger inside the FIOLAX glass barrel was assessed on water-filled 5.5 mL syringes stored at 5°C and 25°C. Average and maximum glide force showed no significant change versus initial performance, confirming stable, predictable gliding over shelf life – a prerequisite for complete-dose delivery and reliable safety system activation within Safe'n'Sound. The functional performance of the syringe in the passive safety system is defined by features including manual passive safety system activation force, force to unload the syringe and needle access distance after use.

"IT IS CRITICAL THAT THE TARGET POPULATION CAN USE THE SYSTEM AND THAT THE MECHANISM DEPLOYS CORRECTLY TO PROTECT USERS FROM ACCIDENTAL NEEDLESTICKS."

Human Factors and Usability

It is critical that the target population can use the system and that the mechanism deploys correctly to protect users from accidental needlesticks. The design of the

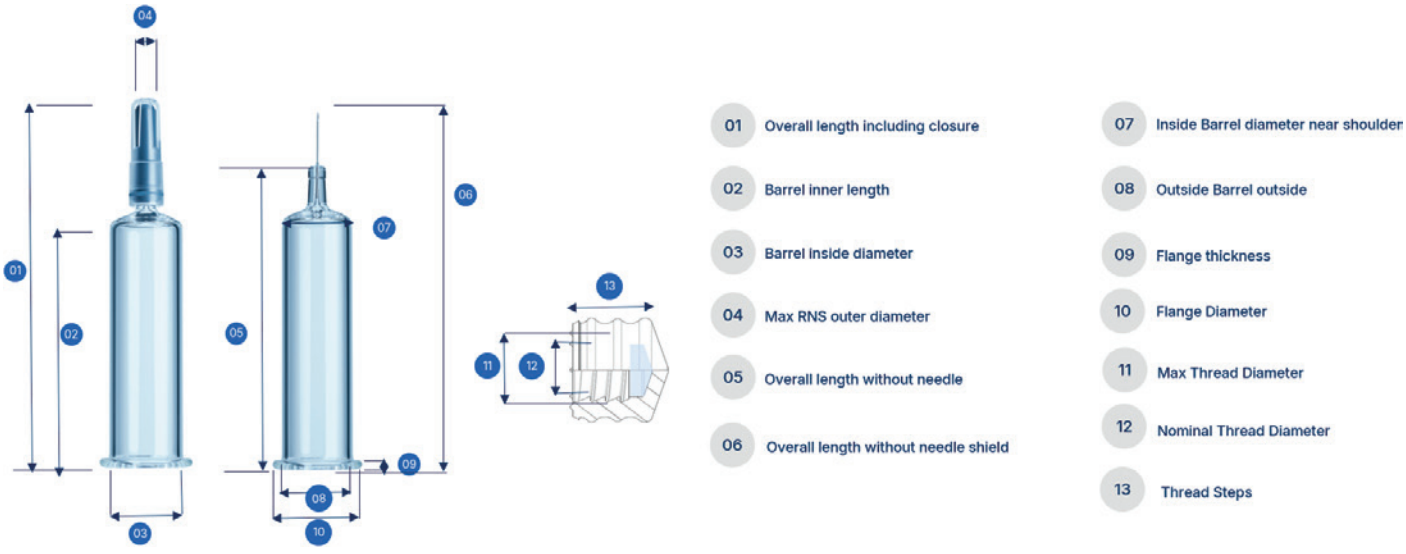


Figure 5: Critical syringe dimensions mapped for syringe-to-device compatibility between syriQ BioPure 5.5 mL and Safe'n'Sound 5.5 mL.

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needle, syringe, safety system and grip features, along with the drug viscosity, directly impact the difficulty performing an injection. Human factors testing evaluated whether the larger volume of 5.5 mL was associated with increased injection difficulty and whether patients could successfully self-administer the 5.5 mL volume with a low-viscosity and a high-viscosity formulation.

HUMAN FACTORS SUPPORTING USABILITY OF LARGE VOLUME

A dedicated human factors study was conducted by Insight by Nemera in collaboration with SCHOTT Pharma to validate the ability of users to self-administer the Safe'n'Sound 5.5 mL with syriQ BioPure in simulated-use conditions. The study enrolled 30 adult participants across two cohorts to reflect the target patient population: 15 users with self-reported hand weakness or dexterity limitations (e.g. arthritis, carpal tunnel syndrome) and 15 users without, including both device-naïve and experienced users.

Each participant completed simulated self-injections into an abdominal injection pad using two device permutations – a 27G 0.5", 6 cP placebo configuration and a 25G 0.5", 20 cP placebo configuration, representing the intended viscosity range – in counterbalanced order (Figure 6), followed by a third scenario using a one-hand pinch grip. Task success was evaluated and supplemented by post-scenario rating-scale questions and root-cause probing of any use errors.



Figure 6: As part of a human factors study, participants completed simulated self-injections into an abdominal injection pad at a 90° angle.

A 90° injection into the abdomen represented a worst-case posture and allowed for robust qualitative assessment of perception of ease of use. Limited visual instructions were provided, but without information on grip technique, to learn how the participants might choose to hold the device intuitively.

Results of the study showed that well-designed manual systems can effectively address the challenges of larger injection volumes. A total of 100% of the

"A TOTAL OF 100% OF THE PARTICIPANTS COMPLETED THE INJECTIONS SUCCESSFULLY WITH BOTH THE HIGH- AND LOW-VISCOSITY DEVICE CONFIGURATIONS, INCLUDING SAFETY SYSTEM ACTIVATION. NO USE ERRORS OCCURRED DURING SIMULATED SELF-INJECTION OR IN SAFETY SYSTEM ACTIVATION."



Isabelle Jeangoudoux

Isabelle Jeangoudoux is the Head of Global Product Management for the Glass Syringe portfolio at SCHOTT Pharma. She started her career in international product management in the automotive industry before transferring to the medical devices industry in 2008. She joined SCHOTT Pharma in 2023 to support innovations, product strategy and device partnerships for glass syringes. Ms Jeangoudoux graduated from ESCEM School of Management Tours (France) with a degree in International Management and Marketing and a Master of Arts in Business and Administration from Bradford University School of Management (UK), Audiencia School of Management (France) and Deusto University (Spain).

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Injection Time (s)			
Condition	**Statistic**	**User Group P**	**User Group H**
Device A 90°	Mean	21	28
	Standard Deviation	15	18
	Max	70	79
	Min	11	10
Device B 90°	Mean	20	27
	Standard Deviation	8	14
	Max	38	51
	Min	11	10
Device B 45° One Hand	Mean	17	27
	Standard Deviation	6	20
	Max	32	81
	Min	9	11

Table 2: Mean injection time was under 30 seconds for all scenarios. User group P included adults without hand weakness or hand dexterity symptoms, while user group H included those with hand weakness or hand dexterity symptoms.

participants completed the injections successfully with both the high- and low-viscosity device configurations, including safety system activation. No use errors occurred during simulated self-injection or in safety system activation. A variety of different grip postures were observed, including two-handed approaches, and were supported by the device design. One hundred percent of participants reported feeling protected by the safety shield.

Participants were instructed to push firmly and steadily, but not "as fast as possible" and injection time was recorded. The mean injection time for the 5.5 mL volume was less than 30 seconds (Table 2). On average, it took participants 24 seconds to inject Device A (27G, 6 cP placebo) and 23 seconds to inject Device B (25G, 20 cP placebo).

When asked to rate their agreement with the statement, "I felt sufficiently protected by the safety shield of the device after I gave the injection", 100% of participants agreed or strongly agreed. The user-centric design of Safe'n'Sound 5.5 mL is supported by this evidence. Testing demonstrated robustness and reliability for large-volume self-administration, supporting patient acceptance.

CONCLUSIONS FOR THE FUTURE OF LARGE-VOLUME MANUAL INJECTION AT HOME

Beyond safety and usability, the integrated syriQ BioPure 5.5 mL and Safe'n'Sound 5.5 mL system is designed to support pharmaceutical companies' drug pipelines end to end, thereby helping secure time-to-market, enabling early preparation for clinical trials and easing the transition from the clinical to the commercial phase. SCHOTT Pharma syriQ BioPure 5.5 mL is commercially available. Not-for-human-use samples of the Nemera Safe'n'Sound 5.5 mL are available for testing and feasibility studies. The full commercial launch for human-use products is expected by 2028.

Compatibility of the PFS and the passive safety system, backed by structured system verification, human factors data and regulatory documentation, helps reduce development risk and avoid the late-stage integration challenges that arise when syringe and device are qualified independently – a clear advantage in the rapidly evolving landscape of large-volume biologics and advanced therapies. As the first fully integrated large-volume passive safety system on the market, syriQ BioPure 5.5 mL with Safe'n'Sound gives biopharma companies a proven, de-risked route to bring high-volume SC biologics to the at-home environment – reducing treatment burden for patients while giving drug developers a faster path from investigational product to approved, commercially supplied combination product.



Léa Salfati

Léa Salfati is a Marketing Category Manager for parenteral drug delivery devices at Nemera, where she leads strategic marketing initiatives across injection platforms, including safety systems, on-body injectors and reusable autoinjectors. She is responsible for market analysis, product strategy, and the development and launch of innovative device solutions in close collaboration with R&D and cross-functional teams. With around 10 years of experience in the pharmaceutical industry, Ms Salfati brings expertise in product marketing, combining business insight with a deep understanding of patient-centric drug-device combination solutions.

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SYNCHRONISED AND OPTIMISED: FOLLOWING THE PATH OF INTEGRATION TO SIMPLIFY SELF-INJECTION DEVICE DEVELOPMENT

Maria Barajas and **Katie Falcone** of **West Pharmaceutical Services** introduce the West Synchrony™ S1 prefillable syringe system and explain how streamlining the design, regulatory and manufacturing processes through an innovative platform that uniquely integrates the syringe barrel, plunger and needle shield/tip cap into a fully harmonised, verified system from a single supplier can improve patient adherence and quality of life.

For patients needing regular doses of injectable therapies, having the means to manage their own regimen can be truly transformational in terms of increased adherence and improved quality of life.

In recent years, increasing numbers of patients have felt these benefits, as pharmaceutical companies and biotech innovators have leaned into the seismic potential of self-administration in at-home settings. By developing technologies and devices that meet this growing demand, drug developers are bringing far greater convenience to patients while simultaneously supporting healthcare professionals and payers by mitigating the burdens of time and cost associated with in-clinic administration.

"THE SIMPLER THE DELIVERY PROCESS, AND THE MORE READILY IT CAN BE ACCEPTED WITHIN THE EBB AND FLOW OF EVERYDAY LIFE, THE GREATER THE LIKELIHOOD OF COMPLIANCE AND THEREFORE ACHIEVING THE DESIRED THERAPEUTIC OUTCOME."

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The logical impact of this enhanced convenience is that patients are better equipped to comply with their prescribed therapies, giving them greater control over the management of their condition and, ultimately, increasing their ability to lead a better life on a more independent basis.

Drug delivery is pivotal in this dynamic, heavily influencing whether the expected benefits of self-administration actually translate into desired human behaviours in the real world. Once a combination product is out in the real world there are many opportunities where the patient experience can be subject to unexpected complications and daily disruptions. In this context, the simpler the delivery process, and the more readily it can be accepted within the ebb and flow of everyday life, the greater the likelihood of compliance and, therefore, achieving the desired therapeutic outcome.

Conversely, if the mechanics of delivery are more complex – such as placing a higher preparation burden on the patient – then there is greater potential not only for delivery errors but also for anxiety, confusion and avoidance.[1]

ADDRESSING HUMAN FACTORS FOR INTUITIVE INJECTIONS

These potential delivery failings underline how the strategic realisation of self-administration must be aligned with a close understanding of real-world patient needs. In an ideal world, these human needs would be answered so fully through intelligent engineering that the act of injecting feels more intuitive than intentional. For the patient, little or no thought is given to the sophisticated mechanics residing beneath the surface of their delivery device, as they are simply not a cause of cognitive burden, friction or concern. Much the same as driving a car, passengers and drivers do not consider the engine/motor, transmission, electrical system, brakes or suspension that are enabling it to move – they are merely sitting and trusting the process.

The contradiction here is that creating an easy experience for patients is far from easy. Indeed, there is a paradoxical relationship between these factors, with ever simpler user experiences intensifying the demand for ever more sophisticated engineering approaches. This underlines the deep complexity of a challenge that involves pulling so many interconnected strands together, including drug formulation, primary packaging and delivery mechanism, all while fulfilling the robust requirements of global regulators.

> "WEST HAS PURSUED AN INNOVATION STRATEGY THAT SIMPLIFIES AND ACCELERATES THE COMBINATION PRODUCT PATHWAY."

Consideration of the desired delivery outcome needs to start from the very earliest stages of drug development. Due prioritisation must be given to the primary packaging system, specifying an appropriate device platform that is suitable for the intended patient cohort. Accommodating reliable drug delivery over the course of a product's lifecycle must also be addressed, and must be based on the specific physical attributes of the formulation.

This gives rise to critical decisions surrounding everything from compatibility of syringe components to precision manufacturing and final device assembly, creating an almost endless list of variables that must be managed to avoid unintended, and often unforeseen, consequences. Material compatibility must be analysed, and dimensional tolerances must be met to ensure that all moving parts coalesce into a precise mechanical sequence and, ultimately, a successful self-injection when the device is in the hands of a patient.

SIMPLIFYING THE PROCESS WITH AN INTEGRATED, VERIFIED PFS SYSTEM

In acknowledgement of the scale of this task, West has pursued an innovation strategy that simplifies and accelerates the combination product pathway. The West Synchrony™ S1 prefillable syringe (PFS) system is an innovative platform that uniquely integrates the syringe barrel, plunger and needle shield/tip cap into a fully harmonised, verified system from a single supplier. Breaking from the component-by-component model of building a PFS, the West Synchrony S1 platform aids pharmaceutical partners with PFS selection through its comprehensive verification data and regulatory packages. This integrated approach streamlines design, accelerates regulatory submission and secures a reliable supply chain from a single accountable supplier, removing the complexity associated with sourcing and testing individual components from different suppliers.

The compatibility between the PFS platform and the patient-controlled injection device is critical to combination product development. West has therefore conducted characterisation studies to demonstrate how the West Synchrony 1 mL long staked needle system configuration can be employed within a range of autoinjector devices from a variety of leading industry providers, meeting critical tolerances for dimensional fit while also demonstrating the desired extrusion forces to ensure reliable, complete delivery of injectable doses. This compatibility provides pharmaceutical partners with a simplified pathway to combination product development built on two established elements: a PFS system and an injection device platform that work together in harmony to form a complete drug delivery solution.

A DIFFERENTIATED EXPERIENCE THAT PUTS THE PATIENT IN CONTROL

The West SelfDose® patient-controlled injector occupies a standalone space in the market as a truly ergonomic self-injection mechanism. With its manual operation and bulbous handle, the device has been specifically designed to facilitate injections among patients who might struggle with dexterity issues. After removing the large bottom cap, users place SelfDose on their skin and push down on the handle using their palm to activate the injection, avoiding the more common requirement to locate and depress a small button. Patient confidence is further amplified by an audible click and a visual absence of the coloured body to signal injection success.

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This user-friendly operation has been a major factor in SelfDose being brought to market with various commercial drugs and indications, particularly demonstrating its suitability in the areas of immunology and neurology. Previous characterisation studies have provided evidence of the device's compatibility with a range of syringes from different manufacturers, and SelfDose has been designed to work with any ISO 11040-compliant syringe with a small round or cut flange.

In manufacturing terms, SelfDose has been designed in a way that streamlines, accelerates and de-risks development. It comprises just four standardised components (top cap, upper housing, syringe retainer and lower sub-assembly) that come together with a PFS in the final assembly stage. This platform structure provides a pre-verified architecture for integrating the device with a PFS, eliminating the time-consuming and costly challenge of building and validating a combination product from scratch.

CHARACTERISING COMPATIBILITY TO EXTEND THE BENEFITS OF SINGLE-SOURCE SUPPLY

West conducted characterisation testing to analyse the compatibility of the SelfDose device in conjunction with the West Synchrony S1 PFS system, assessing whether the pairing of containment system and delivery platform facilitated a successful end-to-end injection experience. The analysis recorded measurements for the following parameters: cap removal force (N), needle protrusion (mm), needle hide (mm), volume delivered (mL) and injection force (N). A total of 30 samples were used for each test, and the results were assessed against established target benchmarks.

In all tests, the performance of the West Synchrony S1 PFS system and SelfDose combination was found to be within the threshold limit, effectively registering a "pass" result across the board. As such, these findings provided clear and robust evidence that, as an integrated offering, the PFS system and delivery device fulfil the essential patient requirements for usability, safety and dose deliverability.

Of course, this testing is not drug specific; every customer will therefore be required to undergo supplemental testing to characterise the complete device constituent part for their own formulation. What it does provide, however, is an important baseline of data that can help inform pharma companies' decision-making

"THESE FINDINGS PROVIDED CLEAR AND ROBUST EVIDENCE THAT, AS AN INTEGRATED OFFERING, THE PFS SYSTEM AND DELIVERY DEVICE FULFIL THE ESSENTIAL PATIENT REQUIREMENTS FOR USABILITY, SAFETY AND DOSE DELIVERABILITY."



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and feeds into the technical documentation required by regulatory bodies.

Moreover, by evidencing compatibility between the West Synchrony S1 PFS system and SelfDose, this characterisation testing shines a valuable light on a simplified pathway for the development of a patient-centric self-injection device. Particularly for companies serving patient cohorts with dexterity issues, it is now possible to wrap consideration of everything from primary packaging to device and delivery into an integrated journey. The confidence that comes with a verified PFS system can be blended with a flexible delivery device to form a combination product with proven credentials.

PROVIDING PARTNERS WITH A PROVEN, PREDETERMINED PATHWAY

This efficient, integrated model provides pharma innovators, biotechs and generics companies with a far simpler pathway to market than if each element were considered in isolation, with findings from essential studies already built-in and necessary information already prepared.

Of course, this does not equate to a "shortcut", "cheat" or "hack". There is no escaping the scientific and engineering rigour associated with developing an effective combination product. And, given the critical scrutiny applied by regulators, submissions must be supported by a detailed dossier of technical data to show that the delivery system as a whole ensures that a drug is contained securely and with integrity, that it can be delivered reliably and safely, and that it can demonstrate efficacy among the target cohort.

Enabling self-administration of an injectable therapy in a way that patients find truly intuitive, uncomplicated and in harmony with the reality of their daily lives may never be an entirely easy task. However, the goal of simplifying and accelerating a development pathway that meets the needs of every part of the ecosystem, from scientist to designer to engineer and patient, is now well within grasp. And that ambition of delivering a truly holistic platform that is synchronised and optimised is becoming an increasingly likely outcome.

West's SelfDose® patient-controlled injector is not independently cleared or approved by any Regulatory Body for general healthcare professional or patient use, nor is it available for general commercial purchase. Its distribution and use are subject to applicable regulatory requirements for clinical investigation, and for marketing authorization, as used in combination with a specific drug or biological product. Each component of a combination product is subject to the requirements established by the Regulatory Body for that component (drug, biologic or device). The regulatory process can be more complicated for combination products including an evaluation of the product characteristics, delivery system and its functionality, intended users and use environment(s), as well as the potential for undesirable interactions between the drug or biologic and the delivery system. As a result, the authors note that the SelfDose® patient-controlled injector's compatibility with any particular drug or biologic must be confirmed, and its ability to achieve the desired patient benefits must also be confirmed, on a case-by-case basis in a manner sufficient to meet Regulatory Body requirements. The assembled appearance of the SelfDose® patient-controlled injector is for demonstrative purposes only. The SelfDose® patient-controlled injector is intended to be distributed as an integrated device and is provided disassembled for assembly with, or around, the specific drug or biologic. Products are shown for informational purposes only. Important product and safety information and warnings are available online.



Maria Barajas

Maria Barajas, Product Management Director for West's Drug Delivery Device team, brings more than 20 years of experience across medical devices, combination products, quality and global operations, with a strong record of cross-functional leadership, strategic execution and commercialisation excellence. Ms Barajas leads customer-focused portfolio strategy and helps shape solutions that advance injectable drug delivery and support evolving patient and healthcare needs. She holds a Bachelor of Science in Mechanical Engineering from the University of Illinois at Urbana-Champaign (IL, US) and an MBA in Global Management from Thunderbird School of Global Management (Phoenix, AZ, US).

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Katie Falcone

Katie Falcone is a seasoned professional with over a decade of experience in the pharma/biotech industry, specialising in parenteral packaging. As Director of Technical Services for the Integrated Systems team at West Pharmaceutical Services, she leads technical collaboration by drawing on her expertise to drive customer success, enable data-driven decision-making and deliver innovative drug delivery solutions.

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THE RISE OF SILICONE-FREE PREFILLED SYRINGES: NEW FUNCTIONAL TESTING CONSIDERATIONS

Landon Goldfarb of **Instron** considers the impact that new alternative and silicone-free coating technologies, developed in response to the challenges presented by the interaction of silicone with sensitive novel biologics, are having on the syringe landscape and how device developers and pharmaceutical companies can ensure the compatibility of these new syringe formats with modern therapeutics and autoinjector systems.

The pharmaceutical industry is currently experiencing a period of innovation and development that has been unparalleled in the past 50 years. New classes of drug products, such as monoclonal antibodies and messenger RNA therapies, are unlocking new potential for patient outcomes and represent a vast opportunity for pharmaceutical organisations.

The demand for these therapies is spurring significant growth in R&D expenditure, manufacturing capacity and primary container development. Specifically, the interface between the primary container and the drug product is being revolutionised due to the known incompatibility between typical surface treatments – such as silicone oil – and large molecule formulations.

Traditionally, silicone oil has been used to ensure reliable device performance, but concerns about protein aggregation and

> "AS SYRINGE TECHNOLOGIES EVOLVE, MANUFACTURERS MUST ENSURE THAT IMPROVEMENTS IN DRUG COMPATIBILITY DO NOT COME AT THE EXPENSE OF DELIVERY PERFORMANCE, PATIENT EXPERIENCE OR DEVICE RELIABILITY."

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the presence of silicone particles impacting efficacy have necessitated new solutions. Syringe developers have responded with the development of novel silicone-free platforms, which can introduce new variables to consider for device performance and necessitate a re-evaluation of functional testing strategies. As syringe technologies evolve, manufacturers must ensure that improvements in drug compatibility do not come at the expense of delivery performance, patient experience or device reliability.

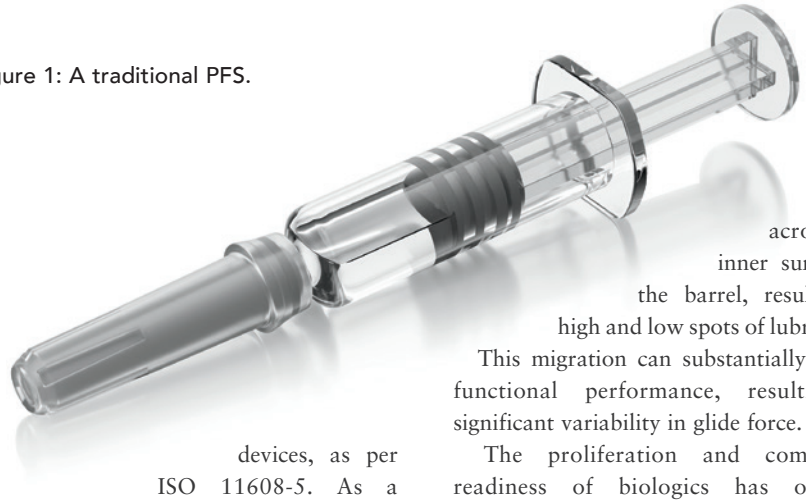
WHY SILICONE BECAME THE INDUSTRY STANDARD

For years, silicone oil was seen as the gold standard for syringe barrel lubrication, addressing many common usability issues. Furthermore, its interaction with more traditional small-molecule drugs was minimal, allowing widespread industry use within prefilled syringes (PFSs) and cartridges.

Figure 1 shows a traditional PFS system. Typically for staked needle syringes, the silicone is sprayed onto the interior of the barrel prior to filling. The use of silicone oil enables more consistent injection forces by ensuring smooth travel of the stopper over the length of the barrel. Previously, syringes were more susceptible to slip-stick performance issues, where the stopper could experience a halting motion partway through the injection, resulting in force spikes and poor usability.

These usability improvements also ushered in the expanded use of autoinjectors, providing more predictable force profiles to design against. Furthermore, spring-based activation mechanisms of autoinjectors could be more easily refined to reach target injection times and reliability requirements for automated

Figure 1: A traditional PFS.



devices, as per ISO 11608-5. As a result, the use of combination products such as autoinjectors became more commonplace within the industry, driven by the increasing prevalence of chronic diseases and patient demand for self-administration options.

CHALLENGES OF SILICONE

As syringe technology matured and a wider body of research was performed, functional drawbacks of silicone oil agnostic to the drug contained within were discovered. Subvisible particle generation is a significant issue that can impact product quality, patient safety and regulatory acceptance. The thin layer of silicone applied to the barrel can undergo mechanical agitation, temperature cycling and ageing, resulting in particles detaching and becoming suspended in the drug product.

This detachment can occur during the manufacturing process, fill-finish operations, transportation, storage – or during activation within an autoinjector. This phenomenon in autoinjectors specifically has become an intensive area of research considering the shear forces experienced during the device's activation.

Another issue is the uniformity of the coating. Over time, the coating can migrate across the inner surface of the barrel, resulting in high and low spots of lubrication. This migration can substantially impact functional performance, resulting in significant variability in glide force.

The proliferation and commercial readiness of biologics has occurred relatively quickly, with biologics now accounting for nearly half of the total pharmaceutical R&D expenditure. Assets are being developed at an unprecedented pace, especially within the areas of oncology and immunology. These new assets bring many new challenges, as they relate to interactions between silicone oil and the drug product.

Biologics have demonstrated vulnerabilities when used in conjunction with siliconised barrels, with concerns around protein destabilisation and the potential for aggregation of particles impacting both the efficacy of the drug and the uniformity of device performance. These risks become more pronounced with higher viscosity solutions – biologics are routinely in the 10–100 cP range.

INDUSTRY RESPONSE

To combat these issues and better position the primary container market to support biologic drug products, innovative solutions have been developed within the PFS space. Established players and new entrants have developed solutions to address these issues, ranging from new coating technologies to completely different container materials.

Many glass-based solutions represent more incremental improvements to existing technologies, with many early developments focused on the coating technology and process. Newer manufacturing processes enable the use of cross-linked silicone coatings or baked-on silicone to limit the amount of particle detachment within the barrel. Many of these solutions avoid significant impact on functional performance but do not eliminate the issue for extremely sensitive biologics.

"ASSETS ARE BEING DEVELOPED AT AN UNPRECEDENTED PACE, ESPECIALLY WITHIN THE AREAS OF ONCOLOGY AND IMMUNOLOGY. THESE NEW ASSETS BRING MANY NEW CHALLENGES, AS THEY RELATE TO INTERACTIONS BETWEEN SILICONE OIL AND THE DRUG PRODUCT."

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Furthermore, manufacturing processes for staked needle syringes, specifically those adhering the needle within the luer cone, cannot withstand the temperatures required for some silicone surface treatments. Beyond the barrel itself, elastomeric components used within the syringe are also being identified as sources of particle generation and are being redesigned without the use of silicone or alternative coating technologies.

Other solutions represent more significant departures from traditional devices, using either silicone-free glass syringes or alternative materials such as cyclo-olefin polymers or co-polymers. These approaches represent a larger shift in container closure technology, one that better addresses the needs of biologics.

These solutions can offer significant improvements regarding drug stability and particle generation, but at the expense of widely understood performance metrics, especially when used in secondary packaging, such as autoinjectors. Each of these newer technologies can fundamentally change how the syringe behaves mechanically, necessitating increased testing and the development of modified design verification programmes.

UNDERSTANDING FUNCTIONAL PERFORMANCE

Pharmaceutical organisations can use traditional equipment, such as universal testing machines, to evaluate and de-risk the use of newer technologies for their drug development programmes. Standards like ISO 11040 and USP <382> remain relevant and drive the methodology for performing these evaluations. Device development teams may modify specific test parameters to serve their particular use case, but will still look to existing standards as a reference point. The following tests are more commonly performed to assess PFS performance:

- Break loose and glide force
- Needle shield and closure removal forces
- Container closure integrity.

The most fundamental assessment of a syringe's mechanical performance is break-loose and glide force testing. Together, these parameters empirically determine

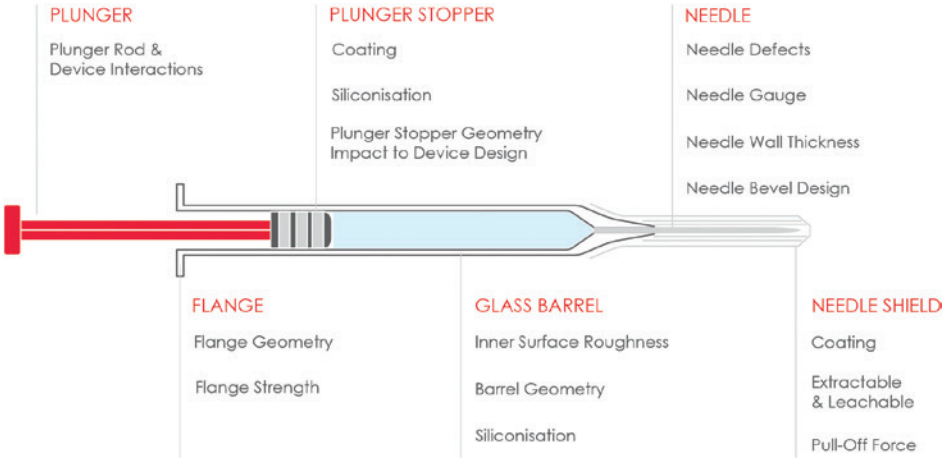


Figure 2: Factors of the syringe that can impact testing.

an assessment of many different device parameters, including coating uniformity, geometric tolerances, stopper coating performance, surface roughness and more.

Figure 2 illustrates many different factors that can impact testing. It is important to note that testing with or without drug products in the syringe will serve different purposes. For purely evaluating the coating performance or for comparison between different syringes, testing will be driven by ISO 11040-4 and should be done without fluid in the barrel. To better understand the interaction between the syringe and the final drug product, taking factors like formulation viscosity into account, testing will be driven by ISO 11040-8 and require the complete combination product.

At their most basic, break-loose and glide force tests represent the forces necessary to initiate plunger movement followed by the force needed to sustain it. These are analogous to the static and dynamic coefficients of friction between the stopper and the barrel. Figure 3 displays a typical graph for this test, which often shows an initial peak representing the break-loose force, followed by a plateau, representing the glide force. The end of the curve can often show a large spike in force, where the stopper engages with the end of the barrel.

In general, the break-loose force should be larger than the glide force, and any unexpected increases in force throughout the glide region can indicate a coating performance issue or a manufacturing error that should be investigated further. These values should be analysed when evaluating silicone-free or alternative silicone technologies to understand any differences in the force profile.

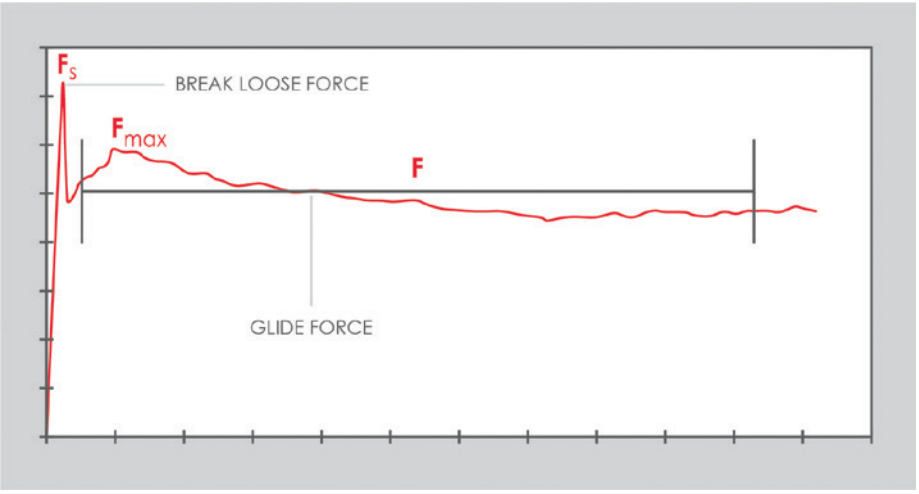


Figure 3: Typical graph of a break-loose and glide force test.

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One of the key parameters that can impact the results is testing speed. Most of the standards suggest a speed of 100 mm/min. However, considering the expected end use of the product or insights from human factors studies, alternative speeds can be suggested. This can become especially relevant when testing with drug formulations that exhibit shear thinning or thickening. In those cases, the plunger velocity will have a significant impact on the measured forces, particularly for the break-loose force.

The use of human factors studies to dictate testing speeds can provide a range of speeds representative of real-world data. In these cases, it might be beneficial to test speeds that represent the outliers of the patient population. Selecting a testing speed should be done based on test objectives and whether the test is intended to evaluate an empty barrel or a filled syringe.

Another factor to consider is the impact of fixturing on the test results. Especially when testing without a plunger, ensuring alignment of the barrel to the probe is crucial. Misalignment, either concentric or angular, can influence the force profile and result in excessive variability in the results. Fixturing should enable the operator to repeatably place the syringe into the test space and minimise the influence of operator action on the results. Figure 4 shows a device held in place with a universal syringe fixture, designed to support a range of syringes from 1 to 50 mL.

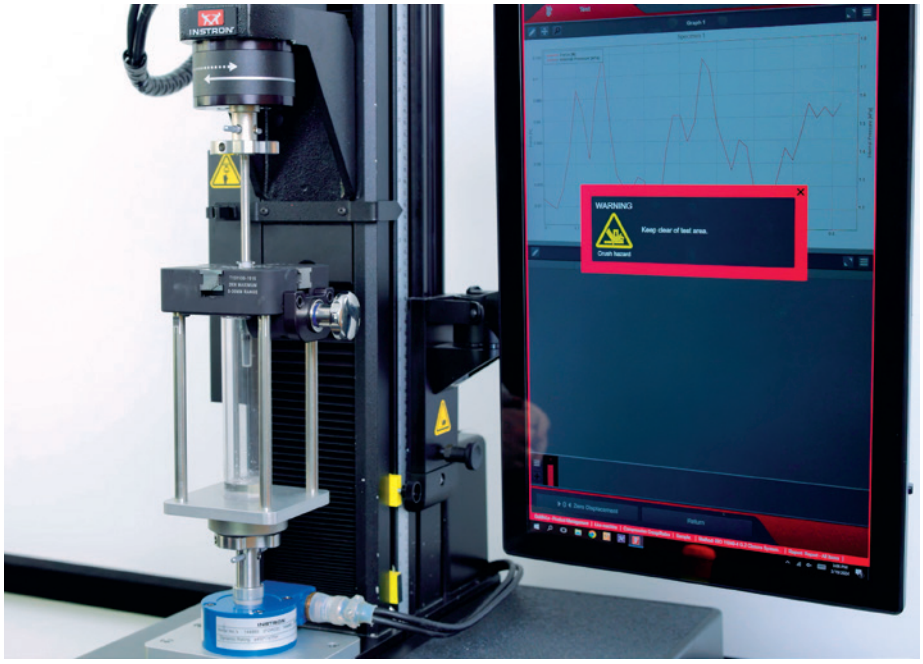


Figure 4: Instron's universal syringe fixture.

IMPACT ON AUTOINJECTOR PERFORMANCE

Many newer syringe technologies are being developed specifically for use within autoinjector devices. Increasingly, device packaging can be seen as a form of differentiation within the market, especially when considering the number of biosimilars and other generics being launched globally.

These newer PFSs may have significant impacts on autoinjector performance and therefore necessitate design changes. Even though a syringe may perform well individually, it may behave differently once integrated within an automated device. The latest update to ISO 11040-8 includes revised verbiage and a new test (Annex D – Administration Time) that is designed to evaluate how a syringe may perform within an autoinjector, indicating an increased emphasis on combination product considerations.

As discussed earlier, changes to the injection force profile can occur, which will necessitate assessment of injection duration, delivered volume, device reliability and, ultimately, spring performance. Most traditional autoinjectors use a spring to depress the plunger and deliver the dose. The interaction between the drive spring and the syringe is a primary determinant of autoinjector delivery performance.

Parameters such as spring force, break-loose force and glide force directly influence key essential drug delivery outputs, including injection time, delivered dose and successful dose completion. These outputs are central to design verification activities and are commonly included in regulatory submissions. Using a semi-automated system as shown in Figure 5 helps to consolidate these tests into a

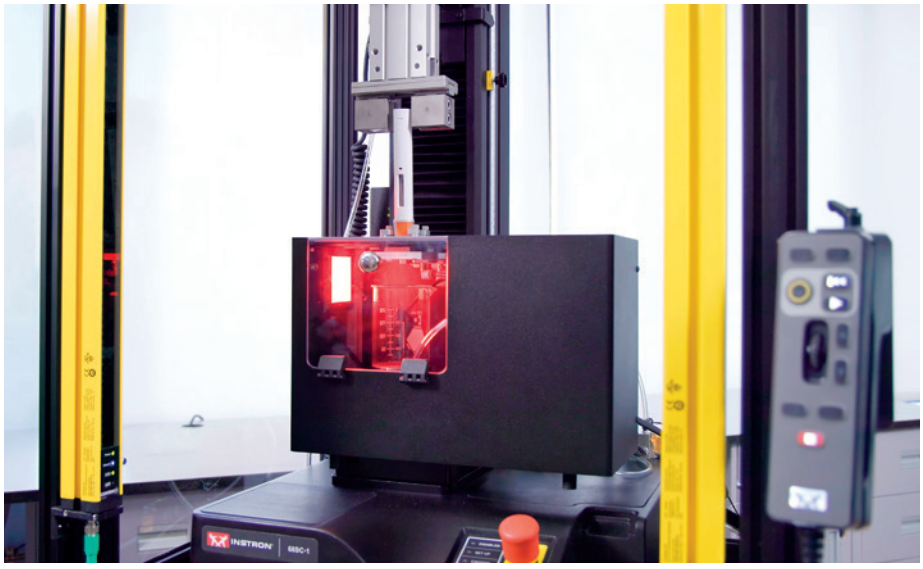


Figure 5: Instron's autoinjector testing system.

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single sequence and reduce the testing burden on early device development teams that are determining the feasibility of these devices with newer syringe technologies.

BUILDING A TESTING PROTOCOL

Developers of any test protocol should holistically evaluate the impact that newer syringe technologies may have on the finished product. The following list is not exhaustive and is primarily focused on mechanical testing requirements rather than non-destructive tests:

- Performance characterisation:
  - Break-loose force
  - Glide force
- Challenge Testing:
  - High/low temperature
  - Simulated shipping
  - Long-term storage (ageing)
- Device compatibility:
  - Combination product performance:
    - Activation force
    - Injection time
    - Delivered volume.

Another consideration is the use of automation to perform this testing. Automation can allow for increased sample sizes with similar resources, improving confidence in the data generated. Additionally, variability in results can be reduced by removing the operator from the equation, especially for mechanical testing where syringe placement in the fixture can have a noticeable impact.

Beyond traditional pick and place, automation can enable sequenced testing to minimise device interactions. For example, performing tests on rigid needle shield removal, injection force and delivered volume in a single sequence can improve throughput and simplify data collection and analysis.

THE CRITICAL LINK: FUNCTIONAL TESTING

Overall, innovation in drug formulations is driving device manufacturers to re-evaluate their products, engineering them for compatibility with novel drug classes. New biologics exhibit high sensitivity to particle generation within traditional siliconised syringe formats. The introduction of alternative coating technologies and non-siliconised syringes can reduce the number of silicone particles and stability concerns but also bring mechanical performance into question.

Functional testing, and specifically mechanical testing, is becoming a critical link between container innovation and successful drug delivery. Partnering with test equipment manufacturers early in development can help pharmaceutical organisations to confidently adopt next-generation syringe technologies while maintaining device reliability and patient experience.

"FUNCTIONAL TESTING, AND SPECIFICALLY MECHANICAL TESTING, IS BECOMING A CRITICAL LINK BETWEEN CONTAINER INNOVATION AND SUCCESSFUL DRUG DELIVERY."



Landon Goldfarb

Landon Goldfarb is Life & Tech Segment Manager at Instron, where he leads a team of market managers and product managers supporting biomedical, electronics and apparel testing applications. He collaborates closely with customers and engineering teams to shape strategy and drive innovation across Instron's static testing portfolio. With extensive experience in highly regulated industries, Mr Goldfarb and his team partner with pharmaceutical and medical device organisations worldwide to advance testing programmes spanning quality control, product validation and R&D.

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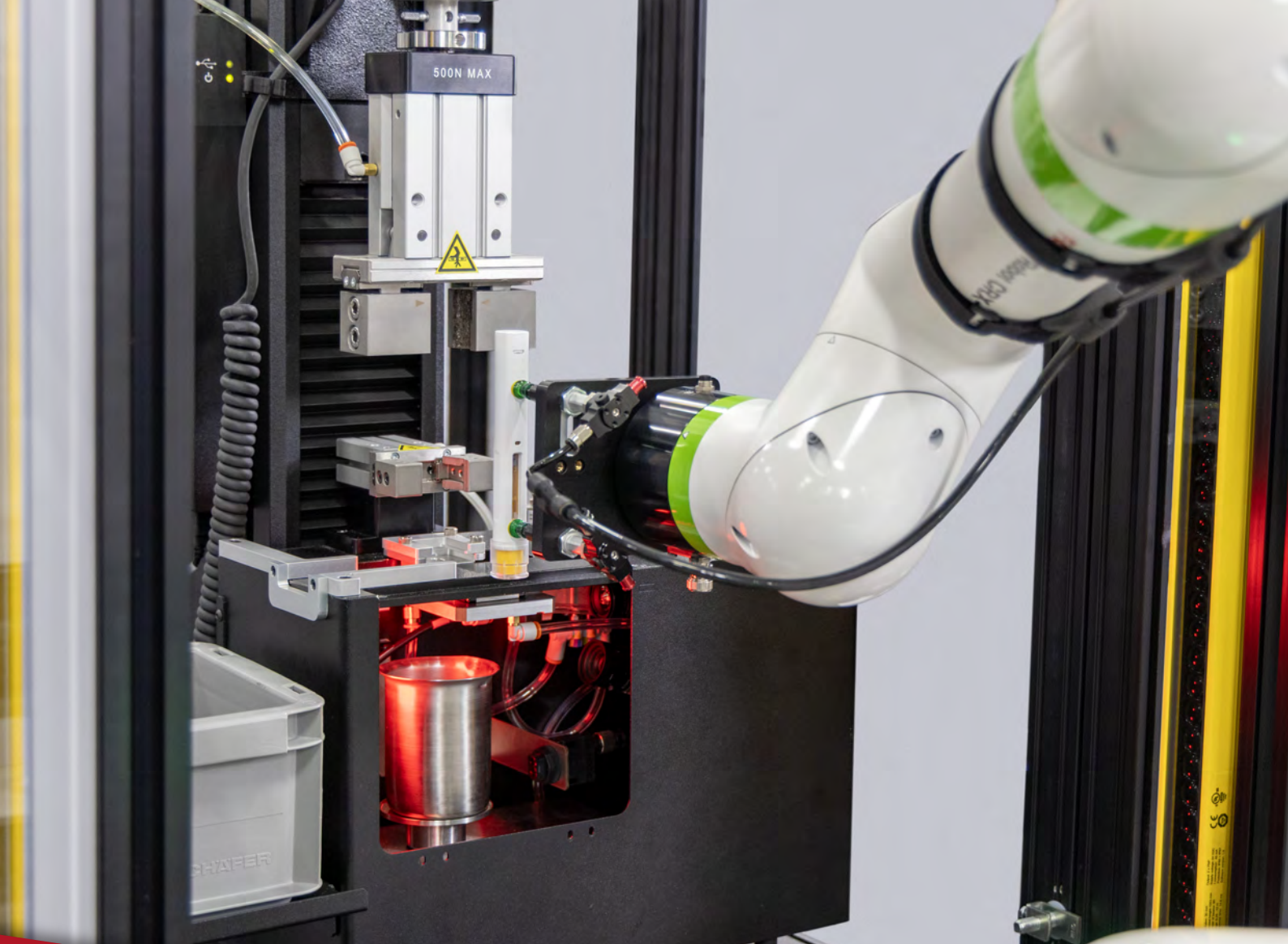
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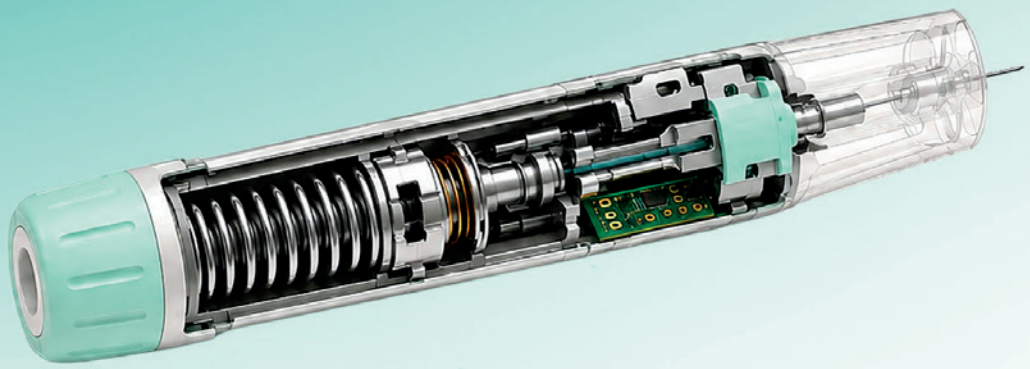
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ENGINEERING THE NEXT GENERATION OF AUTOINJECTORS

Iker Ibisate of **RPK Medical** examines the significant potential of springs and stamped metal components to broaden the design space for autoinjector platform developers by condensing an increasing array of key functions into a minimal number of high-precision parts.

THE AUTOINJECTOR IS BECOMING A SYSTEM

Autoinjectors are no longer simple spring-driven devices designed only to insert a needle and deliver a fixed dose. The advent of biologic drugs, high-concentration formulations, combination products, connected therapeutics and more demanding safety expectations has pushed device designers towards more integrated architectures. Modern autoinjectors must manage force, fluid flow, sequencing, user interaction, electrical functionality and patient safety within a tightly constrained volume. In that context, precision metal components are increasingly becoming a strategic necessity (Figure 1).

"THE ADVENT OF BIOLOGIC DRUGS, HIGH-CONCENTRATION FORMULATIONS, COMBINATION PRODUCTS, CONNECTED THERAPEUTICS AND MORE DEMANDING SAFETY EXPECTATIONS HAS PUSHED DEVICE DESIGNERS TOWARDS MORE INTEGRATED ARCHITECTURES."

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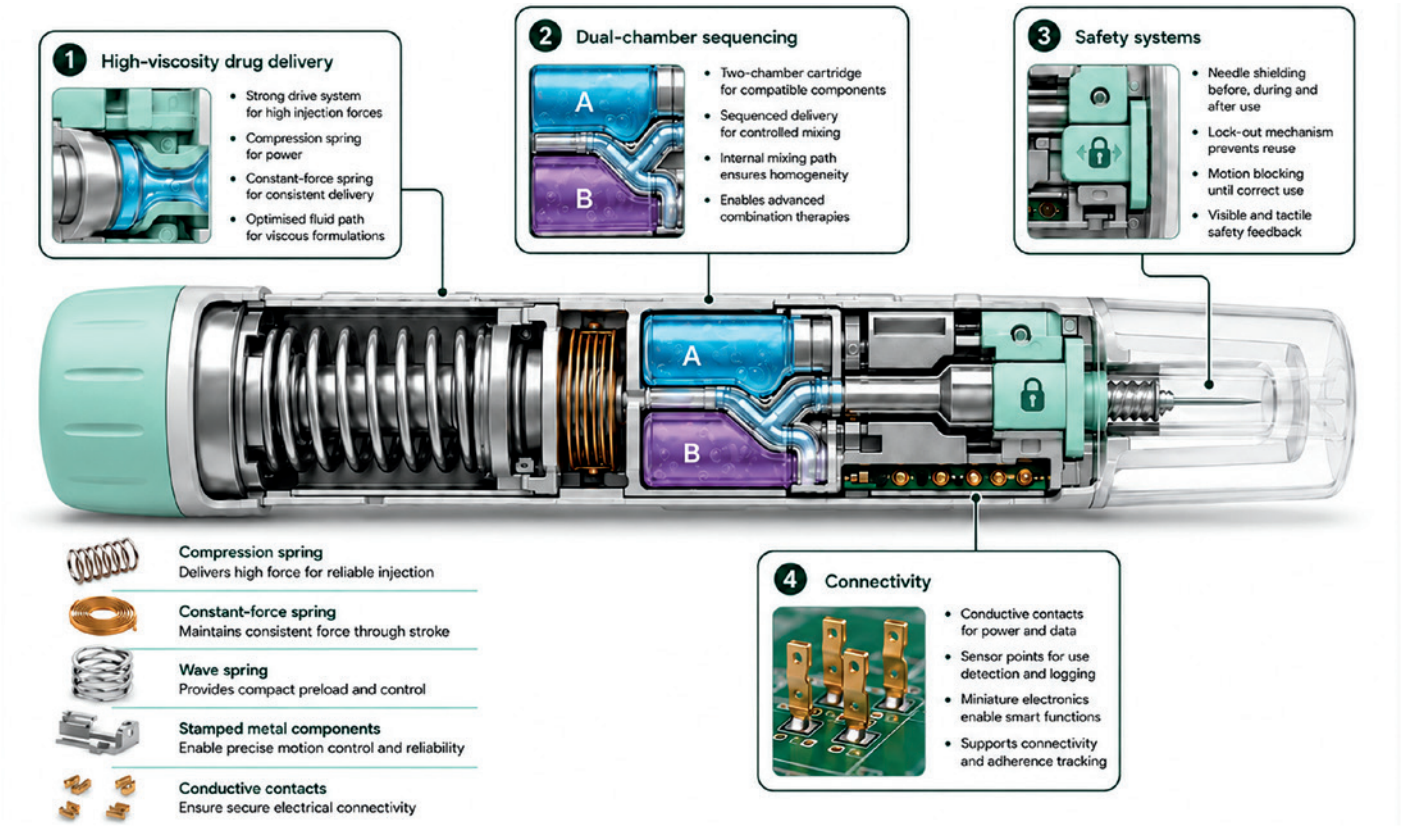


Figure 1: More functionality within the same device envelope – conceptual overview showing how precision metal components support high-viscosity drug delivery, dual-chamber sequencing, safety systems and connectivity within a compact autoinjector architecture.

HIGH-VISCOSITY DRUGS: MORE FORCE WITHOUT A LARGER DEVICE

High-viscosity formulations place immediate pressure on an autoinjector's mechanical architecture. They frequently require higher plunger forces, tighter control of the fluid path and careful management of injection time. Simply increasing size of the drive spring is rarely ideal, as it can enlarge the device, increase the stress on nearby components and reduce design freedom elsewhere in the system. The challenge, therefore, is not only to generate more force, but to do so in a compact, repeatable and manufacturable way.

This is where the selection of spring technology becomes critical. Compression springs remain the most familiar solution for generating high drive force in a compact format. However, constant-force springs can offer a more uniform force profile throughout the stroke, which may help designers looking for more consistent delivery conditions. Wave springs also become attractive when high loads must be delivered within a very limited axial space, such as in preload, retention or compact actuation functions (Figure 2).



Figure 2: Choosing the right spring architecture – comparison of compression, constant-force and wave springs, highlighting how different spring types help designers manage force, stroke length, installed height and motion control.

DUAL-CHAMBER DEVICES: MECHANICAL SEQUENCING BECOMES A DESIGN DISCIPLINE

Dual-chamber and reconstitution devices add another layer of complexity. Instead of a single actuation event, the mechanism may need to co-ordinate several sequential actions: activation, release, communication between chambers, mixing or

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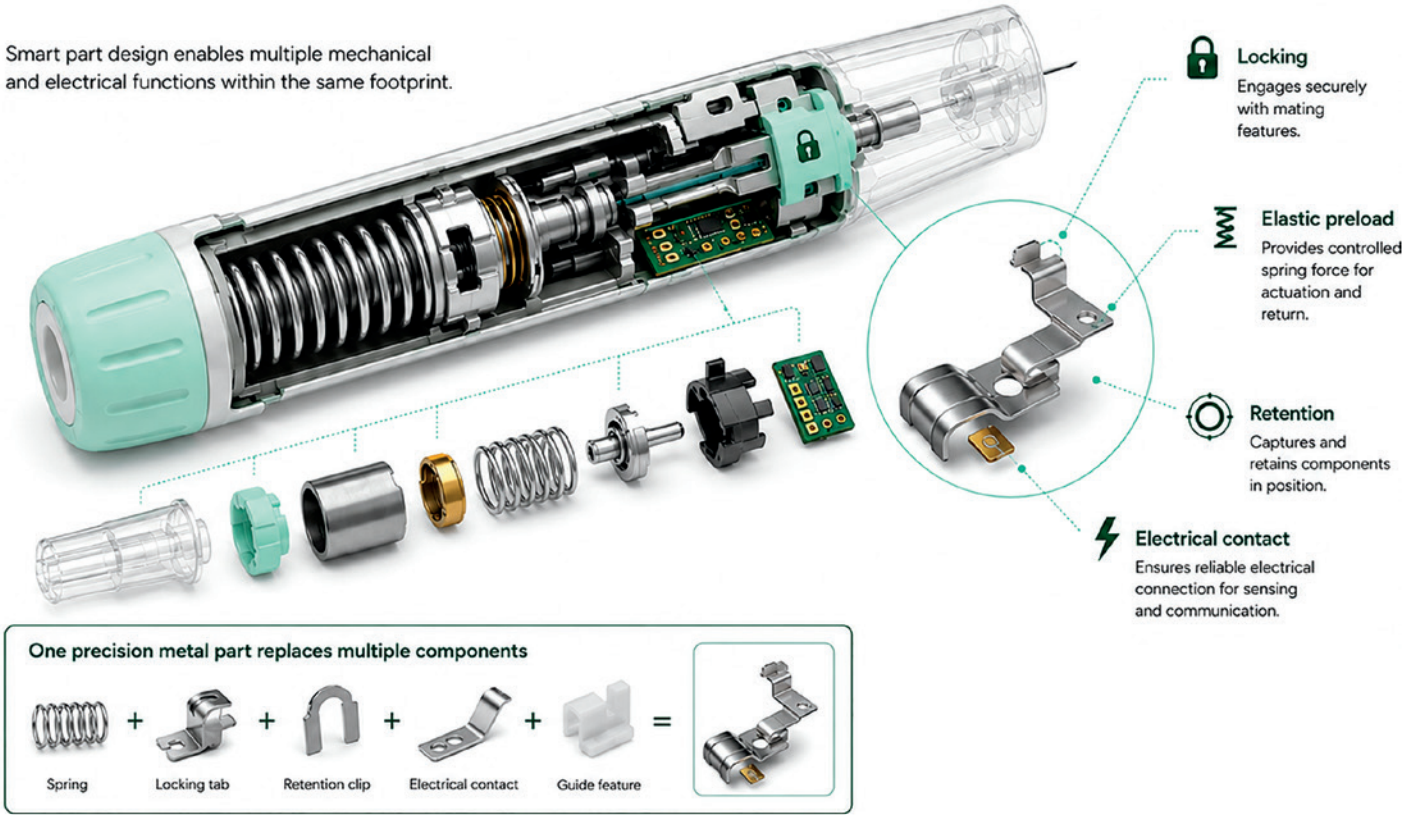


Figure 3: Function integration in a single precision metal part – illustration showing how one precision metal component can combine locking, preload, retention and electrical contact functions, helping to reduce part count and improve robustness.

reconstitution, dose delivery and end-of-use safety. As a result, the internal architecture is defined not only by force generation but also by force timing, release thresholds and motion control. Precision metal parts can help designers mechanically programme these sequences by combining spring energy, retention features, guiding functions and controlled release points into the same assembly.

SAFETY SYSTEMS: ADDITIONAL FUNCTIONS IN THE SAME FOOTPRINT

Needle shielding, lock-out mechanisms, anti-reuse features and tactile or audible user feedback are now expected features of many autoinjector platforms. Each new function competes for space and increases the number of interfaces inside the device. As such, function integration is becoming increasingly valuable. The opportunity is not simply to miniaturise each component, but to combine several functions into a single precision metal part (Figure 3). A well-designed stamped and formed component can simultaneously provide elastic preload, locking, retention, positional guidance and even electrical contact. This approach reduces part count, saves space, simplifies assembly and improves robustness.

MINIATURISED CONNECTIVITY: WHEN ELECTRICAL PERFORMANCE DEPENDS ON MECHANICAL PRECISION

Connectivity is another factor reshaping autoinjector design. Devices are increasingly expected to confirm dose delivery, support adherence programmes, communicate with companion apps or provide traceability over the course of treatment. These functions rely on miniature electrical interfaces that must remain reliable despite tight tolerances, polymer variation and repeated mechanical loading. In practice, miniaturisation makes electrical performance increasingly dependent on mechanical accuracy. Contact force, alignment, repeatability and surface quality become essential. This creates crucial roles for both miniature conductive parts and conventional precision conductive components, whether for battery terminals, sensor interfaces, spring contacts or compact stamped terminals for signal and power transfer (Figure 4).

DESIGN OPPORTUNITY FOR RPK MEDICAL

For autoinjector designers, the opportunity is no longer limited to selecting a standard spring or a standalone conductive clip. The greater opportunity lies in co-engineering more integrated architectures from the outset of development. RPK Group's expertise in precision components manufactured from strip and wire creates a useful toolbox for this challenge:

- High-performance compression springs for power
- Constant-force springs for long-stroke or more uniform force delivery
- Wave springs for compact preload and high force in restricted spaces
- Stamped and formed metal parts for guidance, locking and retention
- Miniature conductive parts for power, sensing and data transfer.

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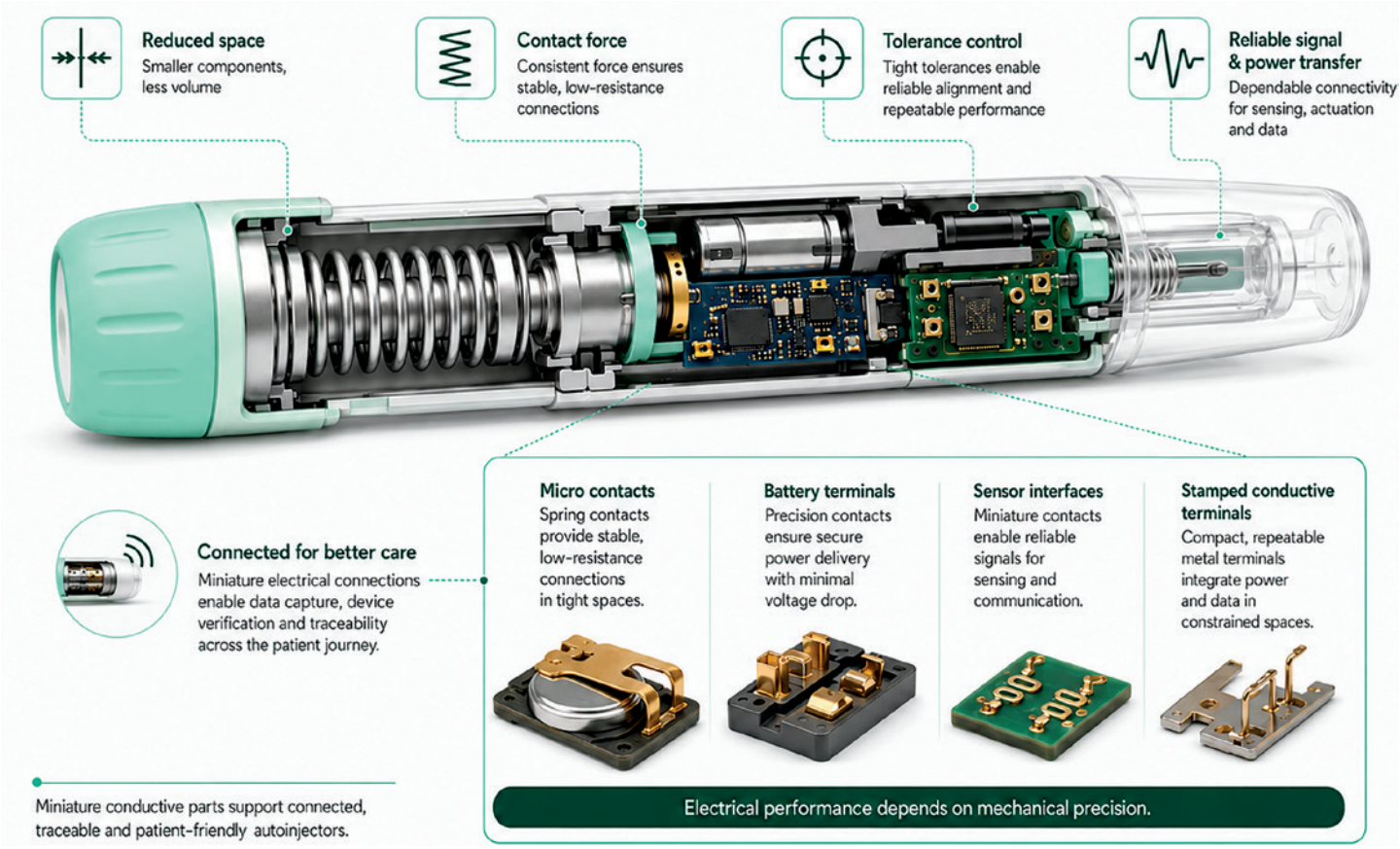


Figure 4: Miniaturised connectivity – illustration showing how micro contacts, battery terminals, sensor interfaces and stamped conductive terminals support connected autoinjectors and how electrical performance increasingly depends on mechanical precision.

Together, these technologies can help device developers increase functionality without proportionally increasing size or complexity.

CONCLUSION

The next generation of autoinjectors will be defined by the need to handle more demanding drugs, more complex mechanical sequences, more sophisticated safety systems and more connectivity capabilities within the same device envelope. That pressure creates a major opportunity for precision metal engineering. By combining mechanical and electrical functions into compact, robust, manufacturable metal parts, device designers can reduce part count, improve reliability and unlock new design architectures. In this sense, the future of autoinjectors will not only be shaped by the drug and the electronics, but also by the intelligence embedded in the smallest metal components inside the device.



Iker Ibisate

Iker Ibisate serves as Head of Stamped and Formed Products for Medical Applications at RPK Medical, bringing over 20 years of experience in product development engineering. He specialises in designing and manufacturing metal components from strip materials, including steel, aluminium and conductive alloys, using advanced multislide-forming technologies. Combining deep technical expertise with a collaborative, client-focused approach, he helps to optimise both design and production costs. His leadership enables RPK Medical to deliver precision-engineered solutions for complex challenges in autoinjectors, such as miniaturisation, controlled drug flow and seamless integration of electronic components, ensuring the safety, reliability and performance of next-generation medical devices.

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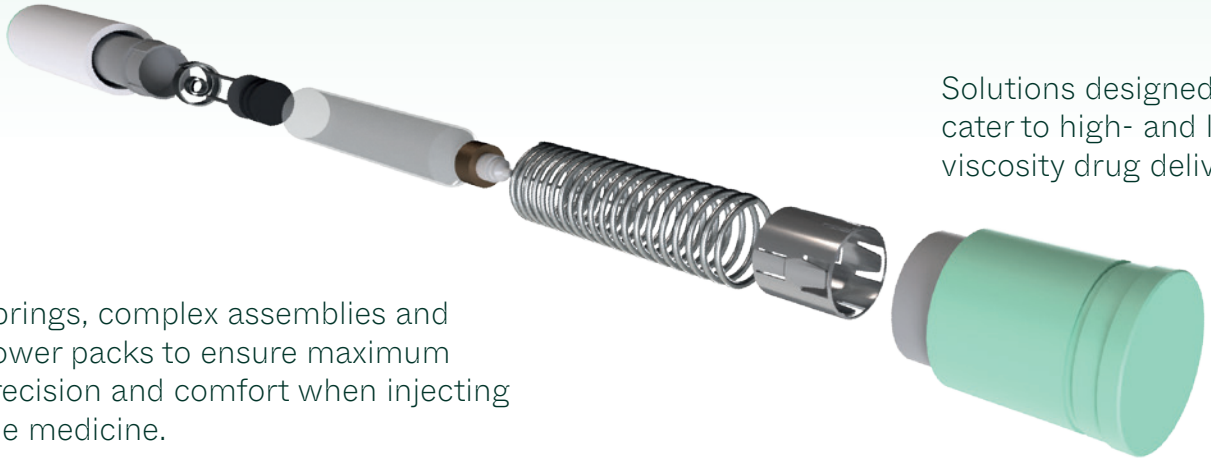
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FROM 3 mL TO 5 mL: EXTENDING AN AUTOINJECTOR PLATFORM FOR LARGER-VOLUME BIOLOGICS

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Moritz Mond and **Dr Reza Abedian** of **Gerresheimer** consider the subcutaneous delivery of larger volumes and higher viscosities, sharing the innovative engineering behind the Gx Inbeneo 5 mL autoinjector concept, designed to offer future developers greater flexibility for drug delivery via a handheld device.

Subcutaneous (SC) delivery of biologics, once largely comprising injections less than 1 mL, is progressively moving towards injection volumes greater than 2 mL. Of 1,338 approved and clinical-stage intravenous and SC biopharmaceuticals, 182 drugs were identified as SC injections over 2 mL. This represents 14% of all biopharmaceuticals, with most being monoclonal antibodies (mAbs) between 2 mL and 5 mL. The large-volume SC pipeline continues to grow, driven by multiple factors such as reduced dose frequencies. This pipeline demands drug delivery solutions that provide similar benefits to smaller volume solutions while addressing the specific challenges of larger volumes.[1–3]

Delivery formats are evolving rapidly for self-administered drugs in volumes of up to 5 mL. Historically, autoinjectors were developed around existing prefilled syringe (PFS) formats and consequently can handle up to 2.25 mL of total injection volume.[4] To deliver larger volumes, formulation scientists must either raise the concentration and find a solution to handle the subsequent higher viscosity, split the dose, move to an on-body delivery device or select an autoinjector that incorporates a larger primary container. Each option has consequences for the drug developer to consider, such as primary container selection, fill-finish process and evidence required for market approval of the combination product.

In the homecare setting, these choices also have significant consequences for the patient. Higher viscosity may impact

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"A KEY QUESTION IS WHETHER AN AUTOINJECTOR CAN BE DESIGNED FOR SAFE AND EFFECTIVE HANDLING OF BOTH HIGHER VISCOSITIES AND LARGER VOLUMES WHILE ENHANCING THE PATIENT EXPERIENCE AND USABILITY."

delivery time, splitting a dose doubles the number of injections and an on-body system can potentially introduce new use steps. A key question is whether an autoinjector can be designed for safe and effective handling of both higher viscosities and larger volumes while enhancing the patient experience and usability.

DEMANDS ON DEVICES FOR VOLUMES ABOVE 2.25 mL

Volume versus Concentration and Viscosity

Drug formulation and device development have multiple interdependencies. While an increase in formulation concentration may help to lower injection volumes, it may also lead to higher viscosities, stability issues or manufacturing constraints. Opting for larger volumes can reduce complexity for formulation development but requires drug delivery devices capable of administering larger volumes. Splitting the dose between two injections via an autoinjector is another possibility, although it adds handling steps and may increase treatment burden.[1,2]

The appropriate trade-off depends on the specific molecule and the capabilities of a given injection device. A device platform that can be configured across a range of volumes, viscosities, needles and delivery times therefore enables greater flexibility for formulation scientists, as they do not need to fix the formulation before the device is selected.

Potential Impact on User Experience

Clinical studies in healthy volunteers have assessed SC injections at volumes above the traditional 1–2 mL range, delivered via various injection methods.[5–7] These studies demonstrate that moderate-to-large volumes can be acceptable under select conditions, but they also show that tolerability is considered in conjunction with injection rate, viscosity, injection site, drug formulation and whether the formulation contains permeation enhancers.

The data are useful for defining a feasibility range, however they do not establish one upper limit that applies to every drug or patient population.[4–7] Bench testing, clinical evidence and human-factors evaluations are required to confirm that an intended formulation can be delivered at an acceptable rate and with an acceptable user interaction.

DESIGNING AN AUTOINJECTOR PLATFORM FOR HIGH-VISCOSITY AND LARGE-VOLUME FORMULATIONS

Gerreseimer's Gx Inbeneo® 3 mL autoinjector platform was developed in collaboration with Midas Pharma (Ingelheim, Germany) to address self-injection of large volumes of highly viscous drugs. The Gx Inbeneo 3 mL is built around a robust prefilled glass cartridge, which raises the accessible volume to 3 mL.

Exceeding PFS-Based Autoinjector Force Limits

In a PFS-based autoinjector, a compressed spring is held by a locking mechanism that must release reliably upon device activation.

"THROUGH COMPREHENSIVE TESTING OF VARIOUS NEEDLE GAUGE AND SPRING FORCE CONFIGURATIONS, GERRESHEIMER HAS DEMONSTRATED THE EFFICACY OF THE GX INBENEO 3 mL PLATFORM TO DELIVER A BROAD RANGE OF VISCOSITIES."

Unlike this method, Gx Inbeneo 3 mL uses a pre-pressurised design in which the spring force is retained by the cartridge and is activated by the opening of the fluid path downstream. This makes a separate spring-locking mechanism redundant, eliminating the spring force impulse at the point of injector activation, while reducing the associated potential of misfiring. As a result of these inherent design characteristics, the platform can employ high spring forces in order to deliver higher viscosities and injection volumes.

Handling High-Viscosity Biologics

In addition to high-spring-force capabilities, Gx Inbeneo uses a double-ended dry needle system. Unlike PFS-based autoinjectors, which use a staked-in needle, the needle is separated from the drug container until the device is activated through a single step of pushing the device against the skin. With the fluid pathway isolated from the drug container during storage, the chance of needle clogging is reduced.

Moreover, this novel double-ended needle helps to balance injection time and the patient experience. The top needle end, which pierces the cartridge septum, has a larger diameter, while the bottom end or the SC needle section, which pierces the patient's skin, has a smaller diameter. This unique design reduces the resistance in the fluid pathway, enabling higher viscosities to be delivered in shorter time compared with those administered through a uniform-diameter needle.

Through comprehensive testing of various needle gauge and spring force configurations, Gerresheimer has demonstrated the efficacy of the Gx Inbeneo 3 mL platform to deliver a broad range of viscosities. For example, 3 mL of a viscous 250 cP solution of water and glycerol was expelled from a 3 mL glass cartridge in 30 seconds, using a 25G needle.[9–11]

Putting Patients at the Forefront

The Gx Inbeneo autoinjector platform was designed to meet the high-performance requirements of larger volumes but was also optimised for safe and reliable self-administration. Straightforward two-step activation enhances the user experience,

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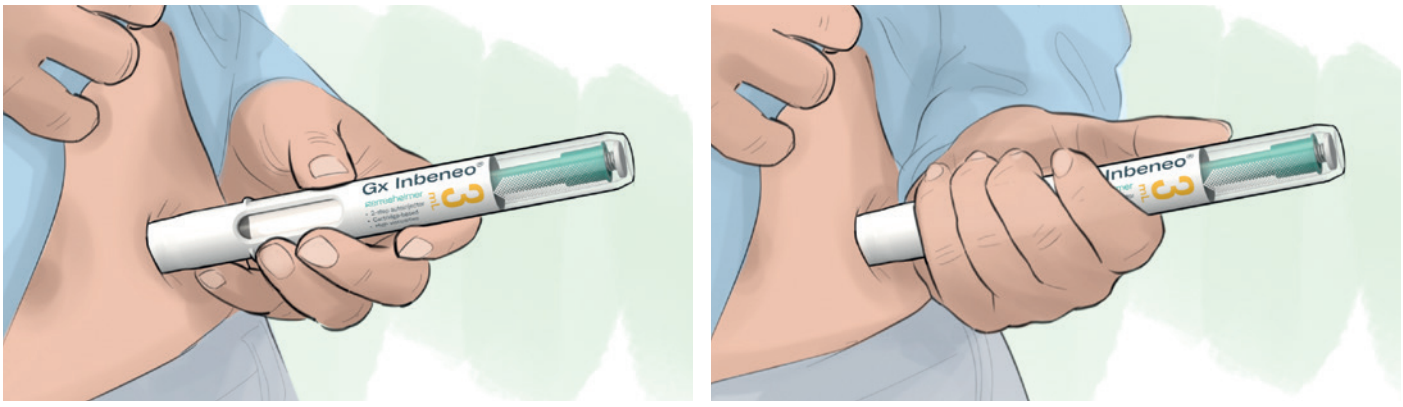


Figure 1: Injection progress can be clearly visualised via the top viewing indicator regardless of grip method.

as the patient simply pulls the cap from the device and pushes it against their skin to begin administration. The standard viewing window in the middle of the device, in addition to a unique transparent top casing, enable the user to track injection progress regardless of the type of grip they use (Figure 1).

Whether using a power grip (holding the device in a closed fist) or a precision grip (using the thumb and index finger) the user can always clearly visualise injection progress. An audible click further confirms dose completion. The double-ended needle design mentioned earlier also presents an advantage to the patient, as it employs a smaller needle diameter at the injection site and therefore reduces discomfort.

"TAKING INTO ACCOUNT THE CARTRIDGE-BASED CONCEPT, STRONG SPRING FORCES, UNIQUE NEEDLE ARCHITECTURE AND USABILITY DESIGNED FOR VARIED INJECTION DURATIONS, THE PLATFORM IS WELL POSITIONED FOR EXTENSION TO HANDLE VOLUMES ABOVE 3 mL."

Studies have successfully demonstrated that users can maintain their grip on an autoinjector over injection durations of up to approximately 30 seconds.[8] Formative user studies conducted by Gerresheimer during development of the Gx Inbeneo reinforced this finding. In one study, 44% of participants rated a simulated injection duration of up to 26 seconds as fully acceptable and 56% as acceptable.

Taking into account the cartridge-based concept, strong spring forces, unique needle architecture and usability designed for varied injection durations, the platform is well positioned for extension to handle volumes above 3 mL.

EXTENDING THE GX INBENEO PLATFORM TO 5 mL

To provide pharmaceutical companies with even greater flexibility when formulating biologics, Gerresheimer has developed a concept for a 5 mL cartridge – a larger volume version of the Gx Inbeneo autoinjector platform that builds on the proven design of the 3 mL version (Figure 2).

Leveraging Proven Architecture

The pre-pressurised, cartridge-based design and actuation method developed for the Gx Inbeneo 3 mL has been carried over to the 5 mL concept. The main differences are a housing with a slightly larger diameter – required to accommodate a 5 mL cartridge – and springs with higher force.

The Gx Inbeneo 5 mL concept encapsulates a 14 mm outer-diameter cartridge, which requires only a slight increase in device size relative to the increase in injection volume. Consequently, in the Gx Inbeneo 5 mL concept, the additional spring force and larger cartridge only increase the device diameter by 2.6 mm with no change in length compared with the 3 mL version.



Figure 2: Gx Inbeneo 3 mL autoinjector platform and Gx Inbeneo 5 mL autoinjector concept.

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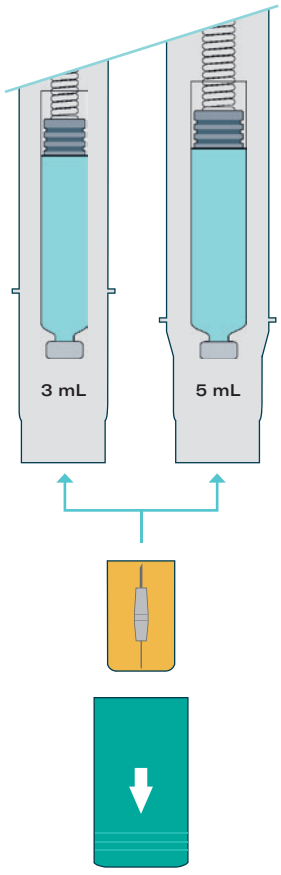


Figure 3: Identical front components used in the Gx Inbeneo 3 mL and 5 mL concept with the rear section adjusted to accommodate a larger cartridge and spring with higher force.

The unique design of Gx Inbeneo decouples the activation and double-ended needle mechanism from the drive spring. This inherent design characteristic reduces the complexity of integrating a new cartridge format. The activation and double-ended needles mechanism on the front end of the device are unaffected by the change from a 3 mL to a 5 mL cartridge. The drive spring at the rear end of the device is scaled in proportion to the larger cartridge diameter (Figure 3). The 5 mL concept is therefore a platform extension around a larger primary container rather than a new device design.

Enabling Flexible Configuration

The Gx Inbeneo 5 mL concept is aimed at drug programmes with doses in the 3–5 mL range that are intended for SC self-administration of viscous formulations. It adds a larger volume option to the Gx Inbeneo autoinjector platform without changing the core architecture or straightforward two-step handling established with the 3 mL version. The concept incorporates a 5 mL cartridge with a fill range of 3–5 mL and standard options of 25G, 27G and 29G for the patient-facing end of the needle. The combination of spring, needle, cartridge and delivery parameters can be selected by a pharmaceutical company depending on the specific formulation and target injection time (Table 1).

	Gx Inbeneo 3 mL	Gx Inbeneo 5 mL concept
Device architecture	Pre-pressurised, cartridge-based design	
Cartridge	ISO 3 mL cartridge	5 mL cartridge (14 mm outer Ø)
Device diameter	19.5 mm	22.1 mm
Device length	196.5 mm	
Patient-facing needle	Double-ended 25G, 27G and 29G as standard	
Usability	2-step autoinjector: pull cap, push to inject	

Table 1: Comparison of features of the Gx Inbeneo 3 mL and the Gx Inbeneo 5 mL concept.

Based on Confirmed Usability

The usability and handling of the 5 mL concept remains consistent with the 3 mL version. The patient simply pulls off the cap and pushes the device against their skin to begin drug delivery. Injection progress can be tracked in real time via the standard central viewing window, or the top viewing indicator and an end-of-dose click confirms successful dose completion. During a formative usability study with the Gx Inbeneo 3 mL, 93% of participants (n=34) rated activation of the autoinjector as easy or very easy. Additionally, 97% of the participants stated that they found it easy to track injection progress, with 66% using the transparent top window for monitoring.

The visual difference between the 5 mL Gx Inbeneo compared with the 3 mL version will be the slightly larger diameter required to accommodate the larger cartridge. The predominant impact on usability may be a slightly longer injection duration. Acceptability would need to be evaluated via a formative user evaluation once the specifications of a drug and device combination have been defined.

Development Readiness

While the Gx Inbeneo 5 mL is a concept in development and has not yet been fully industrialised, the concept may be evaluated through feasibility assessments or co-developed with partners, with final performance and specifications established for each individual drug-device combination. The 5 mL concept provides pharma companies with an additional option during early device selection. Feasibility work will establish how a specific formulation can be delivered within a suitable injection time and confirm that the intended user population can complete drug administration reliably.

CONCLUSION

The pipeline of SC biologic injectables above 2 mL is growing, meaning that the need for safe and reliable autoinjectors to administer higher volumes will only become more evident. Delivering high doses of biologic drugs via self-administration demands an increase in volume, concentration, division of the dose or transfer to an on-body device. Each option has distinct implications for formulation, primary packaging, fill-finish and the evidence required to gain market approval for a final combination product.

In order to maintain a handheld format for large-volume and high-viscosity formulations, the determining factor is the capability of the device to generate and control the force required for delivery within an acceptable injection timeframe to support the user experience. The Gx Inbeneo platform fulfils this requirement through its two-step

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handling, pre-pressurised, cartridge-based architecture and double-ended dry needle. This unique design reduces flow resistance for faster delivery than with a standard needle and removes the risk of needle clogging in storage.

The 3 mL version of the Gx Inbeneo has undergone extensive testing to confirm its technical design, performance range and usability. The 5 mL concept incorporates identical double-ended needles, an activation mechanism and a needle safety shield in the front housing. The rear housing and spring will be adjusted and scaled in proportion to the larger 5 mL cartridge.

As with the Gx Inbeneo 3 mL, the specific patient-facing needle diameter, spring force and resulting injection duration can be configured to meet the criteria for a specific therapy. Feasibility testing and formative evaluations with the target patient population are required to confirm the final design parameters of the combination product. The Gx Inbeneo 5 mL concept therefore offers pharma customers a platform for future co-development projects.



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Moritz Mond is a Senior Product Manager at Gerresheimer where he focuses on the development of innovative drug delivery devices. His expertise spans from a research fellowship at Harvard University (Cambridge, MA, US), through commercialisation of technology developed at university within a startup, to his current role at Gerresheimer in Switzerland.

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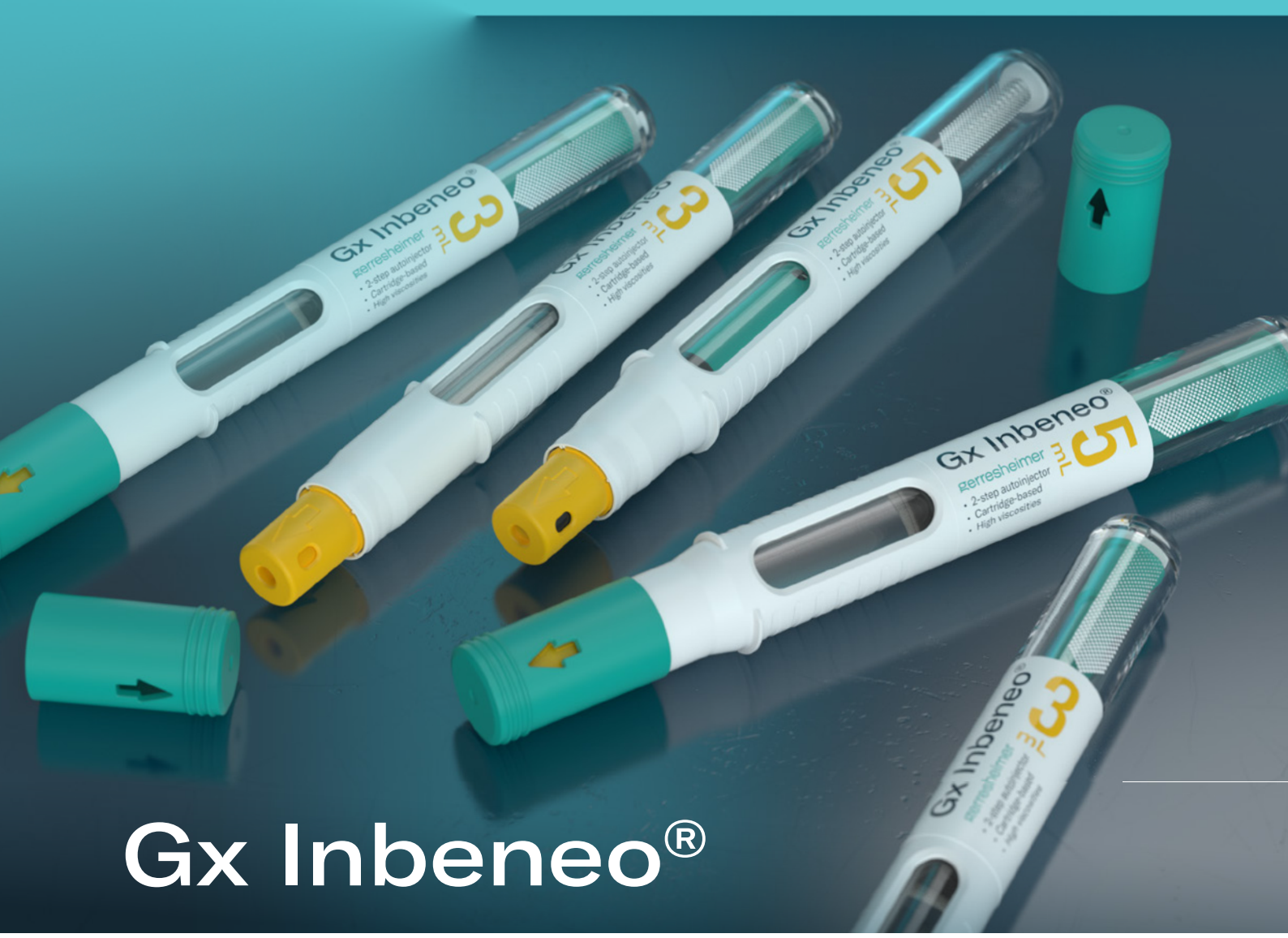
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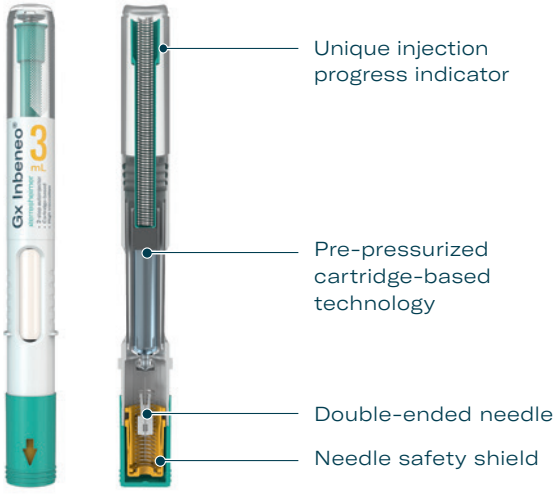
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BUILDING A BIOPHARMACEUTICAL-GRADE PFS: FROM GLASS TUBING TO FINISHED CONTAINER

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Charlotte Leconte-Ostrowski and **Christoph Grinda** of **NIPRO PharmaPackaging** present ENOVIA™, a quality level designed to enhance understanding and achievement of high quality device design for combination products, biologics and biosimilars.

The rapid growth of biologics, biosimilars and new complex injectable therapies is creating new expectations for primary packaging systems. Unlike traditional small molecules, biopharmaceutical drug products may exhibit increased sensitivity to particulate matter, elemental impurities and silicone oil. As a result, pharmaceutical companies are increasingly seeking a deeper understanding of how syringe manufacturing processes influence critical quality attributes.

This article describes NIPRO's journey towards a biopharmaceutical-grade prefillable syringe (PFS) platform. Research activities spanning glass tubing manufacture, syringe conversion, analytical characterisation and functional performance assessment identified several key quality drivers, including dimensional consistency, cosmetic quality, particulate burden, residual tungsten levels and silicone management. By applying an approach for full-process understanding, rather than focusing solely on end-product specifications, NIPRO developed ENOVIA™, a new quality level designed to support evolving requirements for biologics, biosimilars and combination products.

WHY BIOLOGICS ARE DIFFERENT

The pharmaceutical landscape is undergoing a profound transformation. While small molecules continue to dominate marketed therapies today, more than 80% of the current development pipeline of injectable drug products consists of

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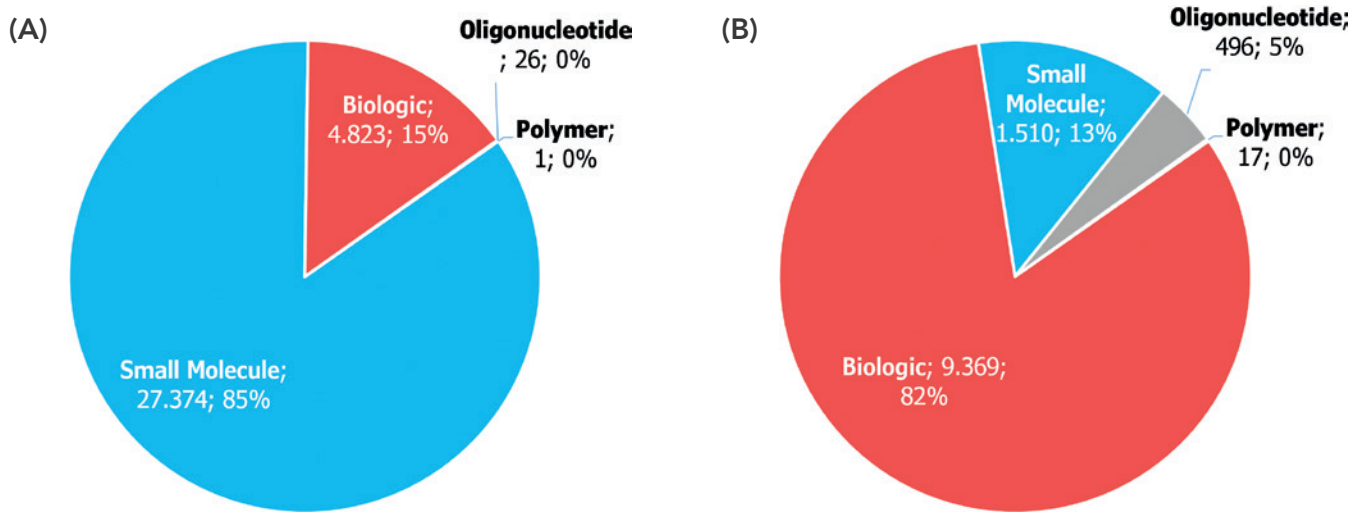


Figure 1: (A) Proportion of marketed drugs for injection divided by molecule type. (B) Proportion of pipeline drugs for injection divided by molecule type.

biologics, biosimilars, oligonucleotides and new complex drug products (Figure 1). New therapies based on such sensitive drug products are expected to drive the future growth of injectable drug delivery systems and, increasingly, are being administered using PFSs and autoinjectors.

Unlike traditional small molecules, biologics are highly sensitive to their environment. Protein aggregation, particle formation, adsorption and interactions with container closure system materials can affect drug stability, efficacy and safety. As a result, biopharmaceutical manufacturers are increasingly evaluating not only the primary packaging configuration itself, but also the underlying manufacturing processes, extractables profiles, particulate burden, residual metal content and functional performance throughout shelf life.

"PROTEIN AGGREGATION, PARTICLE FORMATION, ADSORPTION AND INTERACTIONS WITH CONTAINER CLOSURE SYSTEM MATERIALS CAN AFFECT DRUG STABILITY, EFFICACY AND SAFETY."

INJECTABLE BIOLOGICS ARE RESHAPING DRUG DELIVERY

Historically, syringe quality has often been assessed based on final product specifications alone. However, as biologics have become more complex and drug concentrations have continued to increase, a more holistic approach is required. Every step in the manufacturing chain, from glass tubing production and syringe conversion to ready-to-use processing – including washing, siliconisation, closure assembly and final sterile packing – contributes to the overall quality profile of the finished container.

Recognising these evolving requirements, NIPRO initiated a multiyear development programme to identify the critical factors influencing syringe performance for biologic drug products. The outcome of this work was not a single process improvement, but rather a comprehensive quality concept spanning raw material selection, process control, analytical characterisation and finished container specifications.

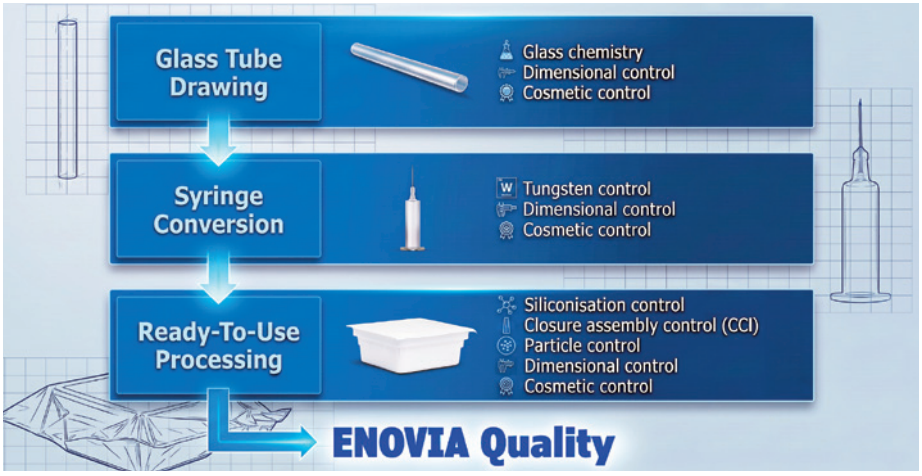


Figure 2: The process to building a biopharmaceutical-grade syringe.

BUILDING QUALITY FROM THE BEGINNING: THE IMPORTANCE OF THE GLASS TUBING

The quality of a PFS begins long before the conversion process (Figure 2). Glass tubing constitutes the foundation for the final container and establishes the dimensional, cosmetic and chemical characteristics that will ultimately influence syringe performance.

For biopharmaceutical applications, glass chemistry must provide consistent hydrolytic resistance while minimising variability. NIPRO's NSV-51 borosilicate

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glass demonstrates stable hydrolytic resistance, supported by the Vello manufacturing process (Figure 3). It also benefits from a heavy-metal-free refining process, resulting in low levels of critical extractable elements, such as aluminium oxide, while also providing excellent pH stability. Together, these attributes contribute to a robust extractables profile and support the industry's increasing focus on the control of elemental impurities and mitigating glass-drug interactions.

Beyond chemistry, dimensional consistency has become increasingly important for high-value combination products. Modern autoinjectors require significantly tighter demands on syringe geometry than traditional manual injectors. Even small variations in outer or inner diameter, wall thickness or ovality can affect fill-finish performance, device integration and functional performance, including dose delivery accuracy and injection time consistency.

To address these requirements, NIPRO has implemented advanced in-line dimensional monitoring systems that continuously measure key dimensional attributes during the drawing process, including wall thickness and outer and inner diameter, enabling targeted tolerances of ±0.05 mm on both outer and inner diameters for selected tubing formats.

Cosmetic quality represents another critical consideration for biologics developers. Defects such as inclusions, air lines and glass cords have traditionally been monitored through sampling-based inspections. However, recent advances in optical inspection technology now enable higher-resolution detection and more accurate in-line classification of cosmetic defects during tubing production. These improvements help to ensure a more consistent starting material, supporting reproducible quality throughout the manufacturing process before syringe conversion even begins.

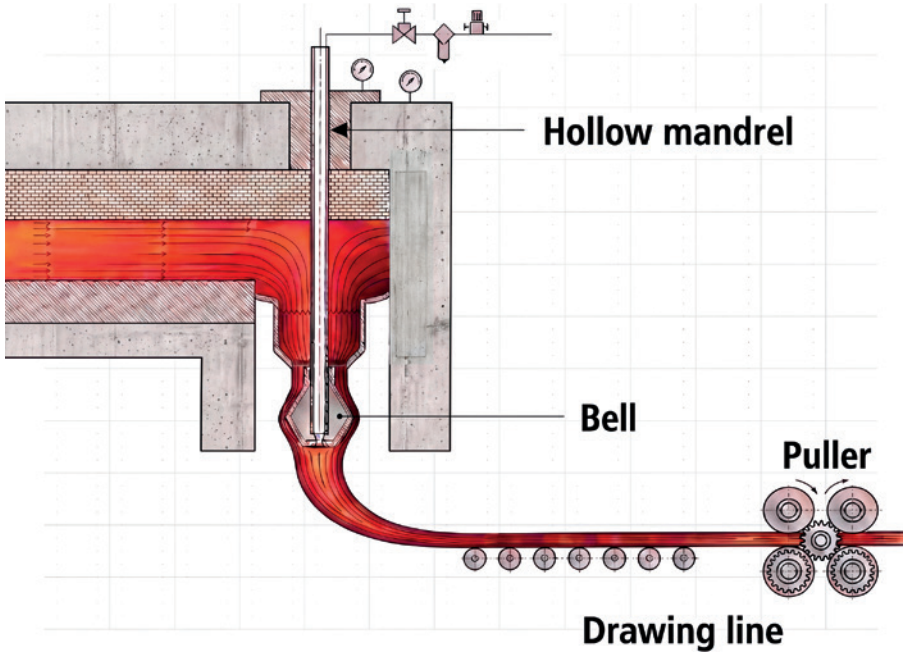


Figure 3: NIPRO's NSV-51 borosilicate glass tubing, manufactured using the Vello process.

For NIPRO, the development of "ENOVIA quality" biopharmaceutical-grade tubing was viewed as the first essential pillar of syringe quality. Establishing a tighter and more consistent raw material specification created the foundation upon which subsequent conversion improvements could be built.

WHY CONVERSION IS CRITICAL

While tubing quality provides the foundation, the syringe conversion process largely determines the final performance profile of a PFS. The manufacture of a staked-needle syringe introduces multiple potential sources of variability, including particle generation, metal residues, cosmetic defects and glass stress. Historically, many of these process variables have been optimised independently. However, biologic drug products require a more integrated approach in which all process steps are evaluated collectively.

To support this objective, NIPRO has developed a dedicated converting line equipped with precision syringe-forming machines, a bulk-washing station, a 100% electric annealing oven with highly stable temperature control and multiple dedicated inspection technologies. This line supports syringe formats ranging from 0.5 to 3 mL.

IDENTIFYING WASHING BEFORE ANNEALING AS A CRITICAL FACTOR

Through a series of development studies conducted across multiple syringe formats, NIPRO identified optimal washing process parameters to achieve ultra-low tungsten levels and reduce particles and water stains originating from upstream conversion processes. Additionally, these studies were designed to assess the impact of the washing process on the quality and performance of the final PFS.

Residual tungsten has long been recognised as a concern for certain biologic formulations because of its potential interaction with sensitive proteins. For this reason, minimising tungsten residues became a key objective of the development programme. Although no globally accepted specification for residual tungsten exists, syringe suppliers increasingly target

"ESTABLISHING A TIGHTER AND MORE CONSISTENT RAW MATERIAL SPECIFICATION CREATED THE FOUNDATION UPON WHICH SUBSEQUENT CONVERSION IMPROVEMENTS COULD BE BUILT."

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low tungsten levels, with advanced biopharmaceutical platforms often aiming for residual tungsten concentrations below 500 ppb.

Using highly sensitive analytical methods, such as inductively coupled plasma mass spectrometry, NIPRO investigated the relationship between forming-pin wear and tungsten extraction levels. The studies demonstrated a direct correlation between pin degradation and measurable tungsten residues. As pin wear progressed over time, extracted tungsten levels increased correspondingly.

These findings enabled the implementation of a proactive control strategy. By combining optimised washing prior to annealing with controlled pin replacement intervals, NIPRO established an ultra-low tungsten process capable of supporting a specification of ≤100 ppb tungsten in the final product, reaching ENOVIA quality. Tungsten-free alternatives for Luer Lock configurations are already available.

SILICONE BALANCING FUNCTIONALITY AND BIOPHARMACEUTICAL EXPECTATIONS

Silicone oil remains essential for syringe functionality. However, the formation of silicone droplets has become an increasing area of focus for biologic drug developers.

To better understand the relationship between siliconisation and syringe performance, NIPRO conducted a comprehensive design-of-experiment study involving multiple parameters, including bulk washing before annealing and silicone quantity, that led to 30 different siliconisation combinations.



Figure 4: NIPRO's new concept – ENOVIA.

Stability data from up to 12 months of accelerated ageing (equivalent to 129 days at 40°C/35% relative humidity) for a 1 mL PFS filled with a test formulation containing 0.01% polysorbate 80 and equipped with a coated plunger, identified two key parameters influencing performance: bulk washing before annealing and silicone quantity. These variables had the greatest influence on glide-force performance while simultaneously positively affecting visible and sub-visible particulate burden levels.

The study also demonstrated that lower silicone levels could be achieved while maintaining acceptable functional performance. Based on these findings, NIPRO developed ultra-low silicone configurations targeting approximately 0.25–0.35 mg of silicone oil, significantly lower than traditional levels. Silicone-free configurations can be provided upon request.

BRINGING IT ALL TOGETHER: THE CREATION OF ENOVIA

The insights gained from tubing development, conversion optimisation and analytical characterisation ultimately converged into a new quality concept: ENOVIA (Figure 4). The ENOVIA quality concept was designed to address the specific needs of biologics, biosimilars and other sensitive drug products. This concept builds on NIPRO's existing quality hierarchy while introducing tighter controls and enhanced

"THE ENOVIA QUALITY CONCEPT WAS DESIGNED TO ADDRESS THE SPECIFIC NEEDS OF BIOLOGICS, BIOSIMILARS AND OTHER SENSITIVE DRUG PRODUCTS."

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specifications where scientific evidence has demonstrated clear benefits.

The ENOVIA concept introduces a new biopharmaceutical-grade tubing specification with tighter dimensional tolerances, enhanced cosmetic and contamination controls, and expanded process monitoring. The quality level also incorporates an additional washing step to reach ultra-low tungsten targets below 100 ppb. Beyond the syringe itself, ENOVIA has undergone validation with best-in-class elastomer components, including rigid needle shields and coated plungers, to support robust container closure system performance.

CONCLUSION

As biologics continue to reshape the pharmaceutical pipeline, expectations for primary packaging performance will continue to rise. For PFSs, quality can no longer be viewed solely as a finished-product attribute. Rather, it is the cumulative result of decisions made throughout the entire manufacturing process, beginning with glass tubing production and extending through conversion, washing, siliconisation and final inspection.

By combining innovations in tubing manufacturing with next-generation conversion technologies, ENOVIA has been designed to support the evolving needs of biologics, biosimilars and complex combination products, while providing pharmaceutical companies with greater confidence in the performance of their primary container system.

> "FOR PFSs, QUALITY CAN NO LONGER BE VIEWED SOLELY AS A FINISHED-PRODUCT ATTRIBUTE. RATHER, IT IS THE CUMULATIVE RESULT OF DECISIONS MADE THROUGHOUT THE ENTIRE MANUFACTURING PROCESS."



Charlotte Leconte-Ostrowski

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Company Showcase

GRAND RIVER ASEPTIC MANUFACTURING

Grand River Aseptic Manufacturing's (GRAM's) operations are focused on a strong commitment to sterile filling. GRAM prioritises patient safety by adhering to strict aseptic standards and collaborating closely with each client, using its extensive expertise to generate optimal outcomes.

GRAM's Sterile Filling Facility One opened in 2020 and features production lines approved by both the EU and the US FDA. The facility has the capacity to produce over 80 million vials as well as more than 10 million syringes and cartridges per year.

"FOR PHARMACEUTICAL COMPANIES, CHOOSING A CDMO GOES BEYOND ASSESSING CAPACITY; IT IS ABOUT FINDING A PARTNER COMMITTED TO QUALITY AND INNOVATION."

Sterile Filling Facility Two is the company's newest sterile filling facility, equipped to provide over 50 million units of syringe and cartridge filling capacity annually, starting with Line 5 (Table 1). This facility includes the infrastructure needed for future expansion to support client needs and meet market demand.

Line 1: Liquid & Lyophilised Vials	Line 2: Liquid Vials	Line 3: Prefilled Syringes & Cartridges
• Bausch+Ströbel • SKAN isolator • 4-head • IMA lyophiliser • 2R, 6R, 10R, 20R, 50R • 20 million units/yr • 6,200 lyo hr/yr • EU/FDA approved	• Bausch+Ströbel • SKAN isolator • 4-head • 2R, 6R, 10R, 20R, 25R • Up to 12,000 units/hr • 20–25 million units/yr • Identical to Line 1 • EU/FDA approved	• Bausch+Ströbel • SKAN isolator • 1/2-head • PFS: 1, 2.25, 3 mL • Cartridges: 3, 5, 10, 20 mL • 1,000–3,000 units/hr • 8–10 million units/yr • EU/FDA approved
Line 4: Liquid Vials	**Line 5: Prefilled Syringes & Cartridges**	**Available Future Space**
• Bausch+Ströbel • SKAN isolator • 8-head • 2R, 6R, 10R • External vial washer • 24,000 units/hr • 40–50 million units/yr	• Groninger • SKAN isolator • 10-head • PFS: 1, 2.25, 3 mL • Cartridges: 5, 10 mL • 24,000 units/hr • 40–50 million units/yr • Media Runs Q1 2027	Space and utilities to support three additional fill lines and client-dedicated projects 

Table 1: GRAM's fill-finish lines.

For pharmaceutical companies, choosing a CDMO goes beyond assessing capacity; it is about finding a partner committed to quality and innovation. GRAM is dedicated to delivering consistent, high-quality sterile fill-finish services that empower pharmaceutical companies in their mission to improve patient outcomes. Specialising in biologics, GRAM's five filling lines serve pharma's liquid or lyophilised vial, syringe and cartridge products.



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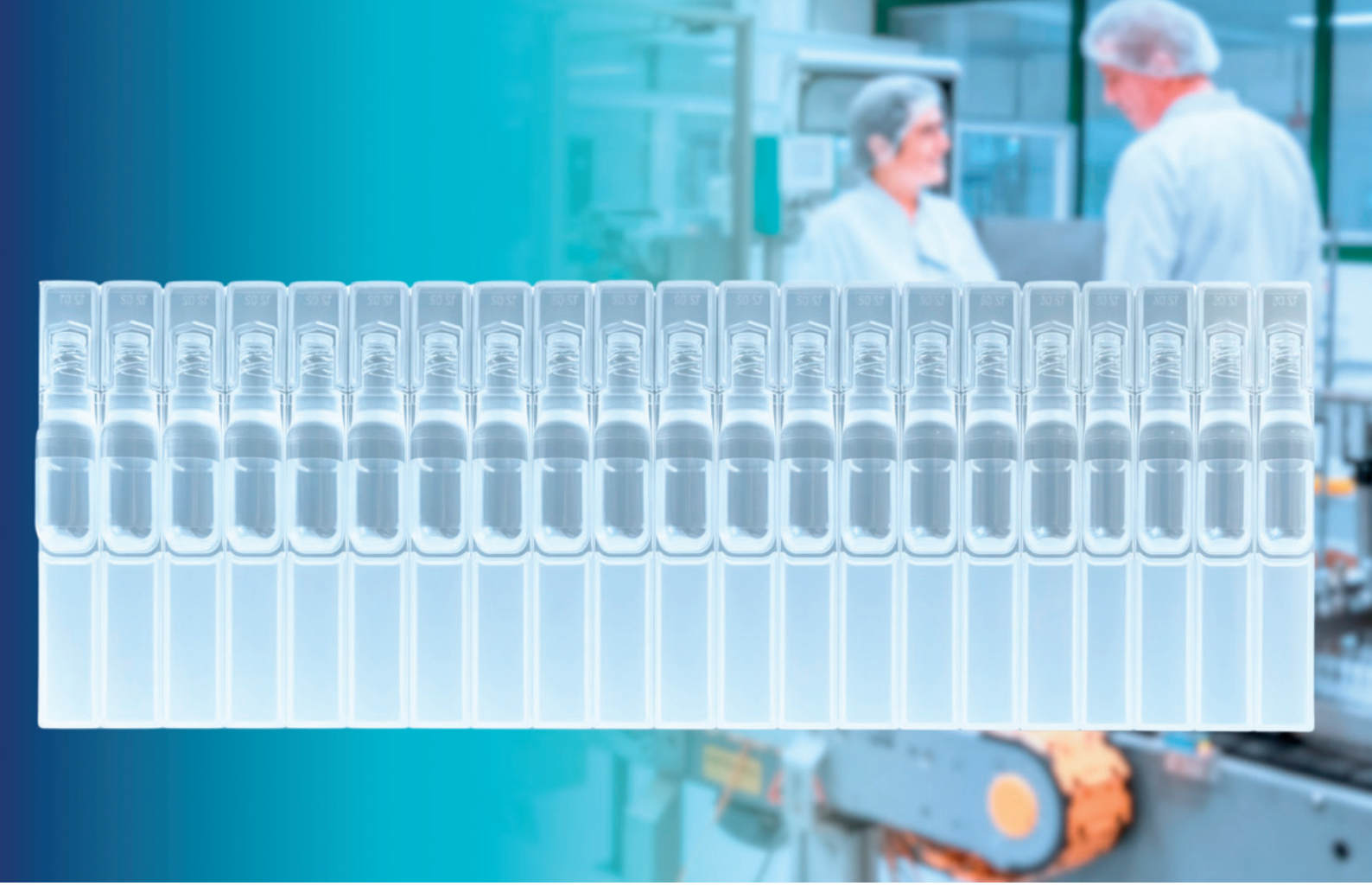
GRAND RIVER
ASEPTIC MANUFACTURING

Selecting a CDMO goes beyond capacity. It's about finding a partner committed to quality and innovation.

To support commercial biologics and enhance patient-centric drug delivery systems, our newest aseptic filling platform is designed for medium- to high-volume production of prefilled syringes and cartridges. This platform ensures that pharmaceutical innovators have the precision, flexibility, and regulatory confidence they need to succeed.

Image of the new sterile filling platform taken during the FAT. Source: groninger





THE EFFECT OF FREEZE-THAW CYCLES ON THE EUROJECT® SYSTEM

Pauline Genovese, **Laury Livemont** and **Dr Alexandre Fontayne**, all of **Unither Pharmaceuticals**, present the findings of nine studies that investigated the impact of freezing and thawing on the company's Euroject® injection system and its ability to deliver the appropriate dose.

Euroject® is a prefilled single-dose injection system developed by Unither using blow-fill-seal (BFS) technology and low-density polyethylene (LDPE). Unlike conventional injectable presentation formats such as multidose vials and most prefilled syringes, Euroject is ready to use and allows drugs to be administered directly without any prior preparation. This simplified administration process may reduce the risk of dosing errors and cross-contamination while decreasing preparation time for healthcare professionals (Figure 1). These advantages are enabled by BFS technology, a fully automated aseptic manufacturing process that supports large-scale production with high operational efficiency.

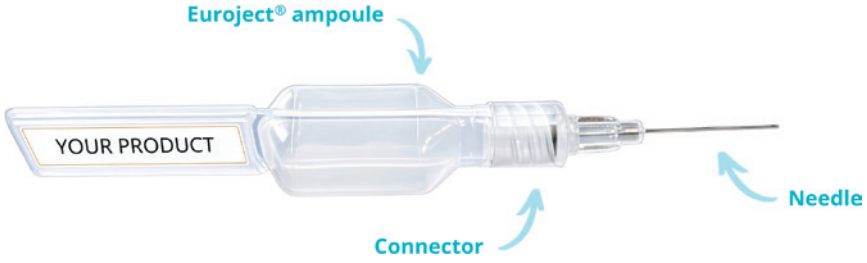


Figure 1: The Euroject injection device and its components.

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Sample name	Condition	Storage condition	Freezing	Thawing	Storage period	Storage configuration
A	Control sample	Room temperature (RT)	RT	RT	Since manufacturing at RT	0 cycle
B	Study 1	-80°C	-80°C	2°C to 8°C	24 hours	1 cycle
C	Study 2	-80°C	-80°C	2°C to 8°C	24 hours/cycle	2 cycles
D	Study 3	-80°C	-80°C	2°C to 8°C	24 hours/cycle	3 cycles
E	Study 4	-80°C	-80°C	RT	24 hours	1 cycle
F	Study 5	-80°C	-80°C	RT	24 hours/cycle	2 cycles
G	Study 6	-80°C	-80°C	RT	24 hours/cycle	3 cycles
H	Study 7	-80°C	-80°C	Oven 35°C	24 hours	1 cycle
I	Study 8	-80°C	-80°C	Oven 35°C	24 hours/cycle	2 cycles
J	Study 9	-80°C	-80°C	Oven 35°C	24 hours/cycle	3 cycles

Table 1: Experiment design – different conditions of freeze/thaw cycles.

With a global production capacity of up to 5 billion doses per year at Unither, Euroject offers a more cost-effective fill-finish solution than traditional multidose glass vials or prefilled syringes. This technology improves access to vaccines and injectable therapeutics by enabling rapid, high-volume production at lower cost, particularly in low- and middle-income countries, thereby contributing to better global health outcomes.

In addition to its operational benefits, Euroject offers significant economic and environmental advantages. The single-dose format eliminates the overfill commonly associated with multidose products, while its lightweight and robust polymer containers reduce the risk of breakage during transport and storage. Furthermore, its recyclable mono-material design and improved cold-chain efficiency contribute to a lower environmental footprint and improved sustainability across healthcare supply chains.

To investigate the impact of freezing and thawing on device performance, a series of nine studies was conducted on the Euroject ready-to-use injection system. The studies evaluated the ability of the device to maintain its mechanical and physical characteristics after repeated freeze-thaw cycles, including during exposure to ultra-low storage conditions at -80°C. Five samples were tested under each study condition (Table 1). The assessment focused on container integrity, device robustness, impact resistance, system tightness and dose delivery performance.

ASSESSMENT OF DEVICE PERFORMANCE AFTER TEMPERATURE CYCLING

Overpressure Integrity Testing

To assess the impact of temperature cycling on the device performance, the integrity of the Euroject system was evaluated through an overpressure test conducted at 3.0 bar, in accordance with connection-tightness requirements.[1] Two different O-ring configurations were investigated to verify the robustness of the vial-connector interface. For all studies and both connection systems, the results were fully compliant, with no leakage detected throughout testing.

These findings demonstrate the robustness of the vial-connector assembly and confirm that the Euroject system maintains its integrity under conditions exceeding normal use, ensuring safe administration and complete product delivery.

Dose Delivery Performance with 22G Needle

Dose delivery performance was further evaluated using the complete Euroject injection system equipped with a 22G needle. Across all nine studies, the delivered volume remained highly reproducible, with delivery efficiencies ranging from 98.1% to 98.9% of the filled volume.

Product losses within the vial, connector and needle assembly were extremely low, ranging from approximately 0.004 mL to 0.007 mL. These results reflect the minimal dead space of the system and indicate that almost the entire dose is delivered to the patient. In addition, no relationship was

"THE CONSISTENCY OF DOSE DELIVERY ACROSS ALL TEST CONDITIONS DEMONSTRATES THAT TEMPERATURE CYCLING DOES NOT ADVERSELY AFFECT THE PERFORMANCE OF THE EUROJECT INJECTION SYSTEM AND SUPPORTS ITS RELIABLE USE FOLLOWING EXPOSURE TO ENVIRONMENTAL STRESS CONDITIONS."

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observed between the number of freeze-thaw cycles and the delivered volume. The consistency of dose delivery across all test conditions demonstrates that temperature cycling does not adversely affect the performance of the Euroject injection system and supports its reliable use following exposure to environmental stress conditions.

ASSESSMENT OF LOW-DENSITY POLYETHYLENE EVOLUTION AFTER TEMPERATURE CYCLING

Dynamic Mechanical Analysis Traction

Dynamic mechanical analysis (DMA) in tensile mode was performed to evaluate the impact of freeze-thaw cycles on the thermomechanical behaviour of the LDPE used in Euroject vials. Tests were conducted between 23°C and 80°C under sinusoidal tensile loading at a frequency of 1 Hz. The storage modulus (E'), which reflects the elastic response of the material, decreased progressively with increasing temperature for all samples, as expected for a semi-crystalline polymer. Comparable E' values were obtained across all conditions, particularly within the 23–40°C temperature range.

At higher temperatures, the control sample exhibited a slightly higher modulus, whereas the sample from Study 6 displayed the lowest values (Figure 2). However, these differences remained limited and did not indicate any measurable change in the overall mechanical properties of the material. Similarly, the loss modulus (E"), associated with the viscous component and energy dissipation mechanisms, decreased gradually with temperature for all samples. Although the control sample consistently showed slightly higher values and Study 6 exhibited the lowest values, the observed differences were minor and did not indicate any alteration in the viscoelastic behaviour of LDPE (Figure 3).

The analysis of the damping factor (tan δ) revealed highly comparable profiles across all conditions. A limited number of samples exhibited small peaks around 60°C, indicating somewhat more pronounced viscoelastic transitions that may be related to localised thermomechanical phenomena (Figure 4). No systematic trend related to freeze-thaw exposure was observed.

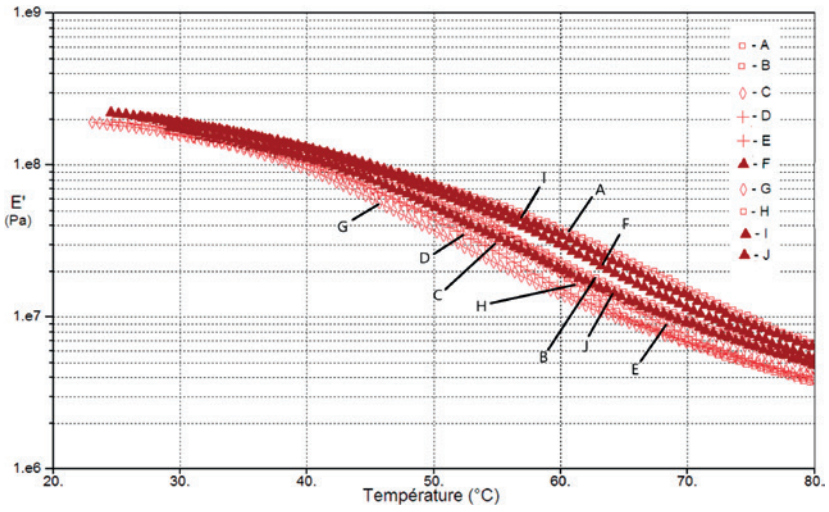


Figure 2: Representation of storage modulus (E') as a function of temperature (°C).

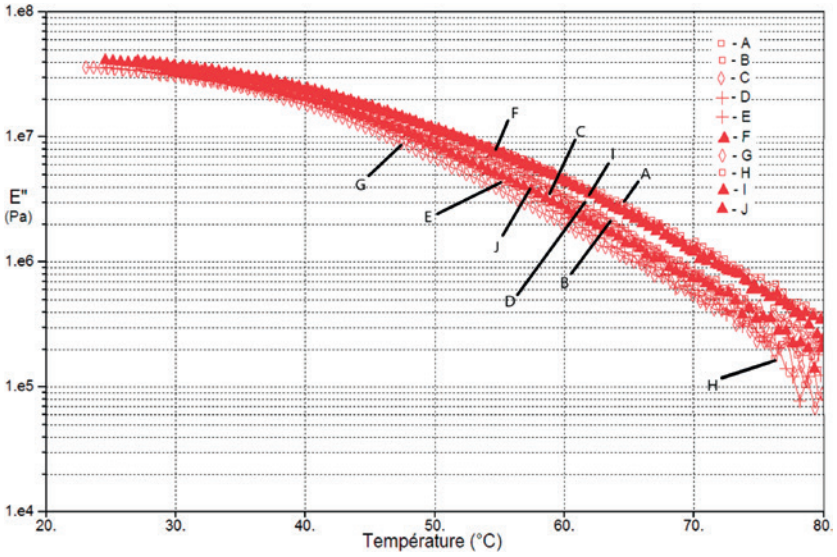


Figure 3: Representation of loss modulus (E") as a function of temperature (°C).

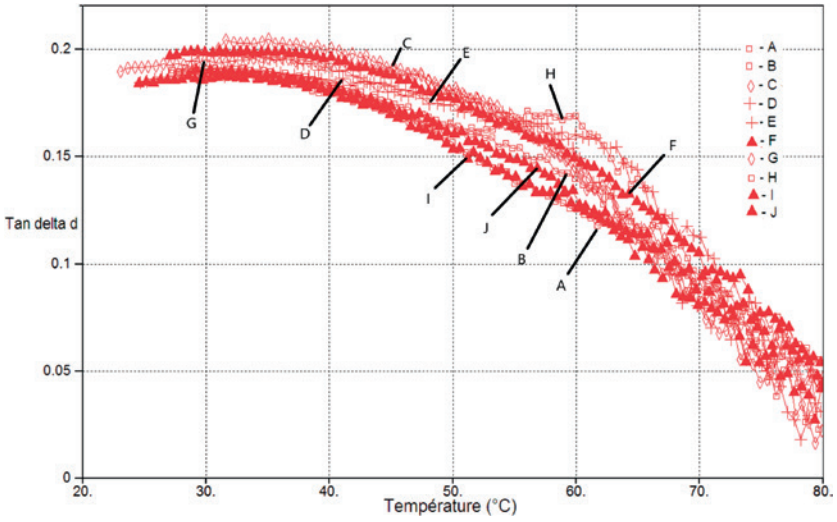


Figure 4: Representation of tangent delta (tan δ) as a function of temperature (°C).

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	Tpm (°C)	ΔH_{fusion} (J/g)	Maximum stress (N)	Deformation at maximum stress (mm)	Stress at failure (N)	Deformation at failure (mm)
Control sample	111 ± 0	116 ± 4	64.8 ± 5.1	6.3 ± 1.3	58.0 ± 2.9	21 ± 5
Study 1	112 ± 1	114 ± 4	65.4 ± 2.7	6.5 ± 0.4	60.0 ± 3.0	20 ± 8
Study 2	112 ± 2	115 ± 2	63.8 ± 2.6	5.9 ± 1.0	60.1 ± 3.3	23 ± 4
Study 3	112 ± 1	118 ± 4	65.1 ± 2.7	6.0 ± 0.5	62.9 ± 2.9	26 ± 7
Study 4	110 ± 0	121 ± 2	68.6 ± 2.8	5.8 ± 0.8	65.0 ± 3.2	26 ± 8
Study 5	110 ± 1	114 ± 4	64.9 ± 4.0	7.2 ± 0.4	59.6 ± 3.9	20 ± 3
Study 6	110 ± 4	118 ± 0	71.0 ± 1.3	5.9 ± 0.7	66.0 ± 3.2	24 ± 2
Study 7	112 ± 1	120 ± 1	69.3 ± 3.0	5.9 ± 0.5	64.8 ± 2.0	23 ± 8
Study 8	109 ± 2	120 ± 2	67.3 ± 6.3	5.9 ± 0.7	64.8 ± 5.2	30 ± 12
Study 9	110 ± 1	120 ± 7	74.7 ± 2.8	5.9 ± 0.5	66.8 ± 3.3	19 ± 4

Table 2: Main performance attributes of the Euroject injection device after freeze-thaw cycles.

"OVERALL, THE DSC RESULTS DEMONSTRATE THAT MULTIPLE FREEZE-THAW CYCLES HAVE NO IMPACT ON THE THERMAL PROPERTIES OF THE BFS-LDPE VIALS."

Overall, the DMA results demonstrate that repeated freeze-thaw cycles at -80°C followed by thawing do not significantly affect the elastic or viscoelastic properties of LDPE. These findings confirm the mechanical stability and robustness of the material under the storage conditions evaluated.

Differential Scanning Calorimetry

Differential Scanning Calorimetry (DSC) was performed on two samples for each freeze-thaw condition to assess the impact of temperature cycling on the structure of the LDPE material used in Euroject vials. During the first heating ramp, the peak melting temperature (T_{pm}) remained highly consistent across all samples, ranging from 109°C to 112°C, compared with 111°C for the control sample. Similarly, the enthalpy of fusion (ΔH_{fusion}) showed only limited variation, ranging from 114 to 121 J/g, versus 116 J/g for the control (Table 2).

As these parameters are directly related to the crystalline organisation of the polymer, their stability indicates that repeated freeze-thaw cycles at -80°C did not induce any measurable changes in the crystallinity or thermal behaviour of the LDPE material. The minor variations observed were within the expected experimental variability and do not suggest any degradation or alteration of the polymer.

Overall, the DSC results demonstrate that multiple freeze-thaw cycles have no impact on the thermal properties of the BFS-LDPE vials. These findings confirm the excellent structural and thermal stability of the material and support its ability to maintain its physical and mechanical integrity under the storage conditions evaluated.

Tensile Testing Across the Parting Line

The tensile mechanical properties of the polyethylene container were evaluated on five specimens per condition using a tensile testing machine operated under controlled environmental conditions (23 ± 2°C, 50 ± 10% relative humidity). The results showed a high degree of consistency in mechanical performance across all tested conditions, with maximum stress values ranging from 63.8 ± 2.6 N to 74.7 ± 2.8 N (Table 2).

Studies Six and Nine, which included three freeze-thaw cycles, displayed the highest measured maximum stress values, corresponding to increases of approximately 10% and 16%, respectively, compared with the control condition. Similarly, the stress at failure was at least 14% higher under both conditions. Although a slight reduction in elongation at failure was observed for Study 9, this decrease remained limited and did not indicate any loss of structural integrity.

Overall, there was no evidence of adverse effects of freeze-thaw cycling on the tensile properties of the polyethylene. The tested material maintained its mechanical performance following exposure to repeated freezing and thawing conditions, including ultra-low temperature storage. These findings suggest that neither the polyethylene material nor the integrity of the parting line area assessed during tensile testing was negatively affected by the applied thermal stresses.

CONCLUSION

The study demonstrates that repeated freeze-thaw cycles, including storage at -80°C followed by thawing, do not compromise the performance or material properties of the Euroject BFS-based prefilled single-dose injection system.

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"THE DEMONSTRATED STABILITY UNDER FROZEN AND ULTRA-LOW-TEMPERATURE CONDITIONS REINFORCES THE VALUE OF THIS BFS-BASED PLATFORM AS A RELIABLE AND VERSATILE SOLUTION FOR INJECTABLE PRODUCTS, INCLUDING VACCINES AND BIOLOGICS REQUIRING STRINGENT COLD-CHAIN MANAGEMENT."

Device integrity was maintained under all tested conditions, with no leakage observed and consistently high dose delivery efficiency (> 98%). Furthermore, DMA, DSC and tensile analyses confirmed the preservation of the thermal, mechanical and viscoelastic properties of the LDPE material following temperature cycling. Taken together, these results highlight the robustness of Euroject and its ability to withstand demanding storage conditions without loss of performance. The demonstrated stability under frozen and ultra-low-temperature conditions reinforces the value of this BFS-based platform as a reliable and versatile solution for injectable products, including vaccines and biologics requiring stringent cold-chain management.

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Pauline Genovese

Pauline Genovese is a Development Projects Manager at Unither Pharmaceuticals, and has led project development since October 2025. She previously worked as a consultant for pharmaceutical companies such as Takeda and GSK in Belgium where she was involved in vaccine development. Ms Genovese holds a degree in Health Engineering from Université de Picardie Jules Verne (Amiens, France) and an engineering degree in Biotechnology with an entrepreneurship and R&D speciality from Sup'Biotech Engineering School (Villejuif, France). Passionate about innovation, she chose to make it her career to contribute to technological advances in healthcare and pharmaceutical products.

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Laury Livemont

Laury Livemont currently serves as the Group Development Projects Manager at Unither Pharmaceuticals. An experienced project manager in the pharmaceutical industry, she has led the Euroject project since 2021. With over 20 years at Unither, Ms Livemont has held roles such as Corporate Project Manager and Pharmaceutical Development Manager. Her career also includes positions at Auchan and L'Oréal, where she developed new products and managed quality assurance. Ms Livemont holds an engineering degree in Chemistry from École des Hautes Études d'Ingénieur (Lille, France) and a Management Diploma from Institut Français de Gestion (Paris, France).

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Dr Alexandre Fontayne

Alexandre Fontayne, PhD, has worked for Unither Pharmaceuticals as Chief Scientific Officer for biological products since 2021 and is deeply involved in the development of the Euroject device. He received his PhD in Biological Science at Université Paris Sud (Paris, France) and has over 20 years of experience in research and development, including 13 years in the pharmaceutical industry working on drug design and production of biologics, such as ublituximab. Dr Fontayne is co-author of 28 scientific articles and holds 12 patents. He contributes to the training of students and employees in drug design, chemistry, manufacturing, and controls activities and subcontracting.

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BRAND NEW TITLE LAUNCHING 2027 ON diagnostics

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Interview: PRIME NEXUS: Advancing the Autoinjector with the Power of Software

In this exclusive interview, **Dr Patrick Anquetil** of **Portal Instruments** sits down with ONdrugDelivery's Guy Furness to talk about how Portal and the drug delivery industry have changed since the company was first founded over a decade ago and the significant unmet need in injectable drug delivery around the 5–10 mL volume range. Dr Anquetil explains how Portal's electromechanical PRIME NEXUS platform uses software to solve challenges in this space that springs simply cannot, and how devices such as PRIME NEXUS are set to meet the expectations of the future.

Q Springs have been the core of autoinjectors for decades – why introduce software into something that already works?

A To start at the beginning, Portal started out as a needle-free injector company. Ten years ago, it wasn't as clear as it is today that the public would accept autoinjectors; after all, since the invention of the hypodermic needle, patients have never liked being injected. So we started out with the question "Can we go beyond the needle?" This was the hardest drug delivery problem at the time.

However, as the industry has evolved, we've changed along with it. Developing a needle-free delivery system doesn't seem like the solution to the industry's challenges the way it did a decade ago. What we ultimately discovered was that the real breakthrough wasn't needle-free delivery itself; it was the electromechanical platform we developed along the way.

That's been a powerful insight. We realised that we didn't need to be needle-free to access the benefits of our PRIME NEXUS platform. Its closed-loop control, on-demand power and precisely tailored injection profile are all driven by software. That's what makes PRIME NEXUS fundamentally different – and uniquely suited to the industry's move beyond 2 mL biologics.

As you know, with some of the drugs coming out of pharma pipelines today, 2 mL is already too much volume to handle for a spring-based device to then deliver consistently. If you go beyond 2 mL, that problem only compounds. The spring can't keep up.



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Patrick Anquetil, PhD, is Founder and Chief Executive Officer of Portal Instruments, leading a multidisciplinary team of engineers, scientists and business professionals dedicated to revolutionising injectable therapies with connected, reusable drug delivery solutions. His focus is on enhancing the patient experience and improving adherence to injectable therapies. With over 20 years of experience in the medtech and biotech industries, Dr Anquetil has a proven track record of innovation and strategic execution. Under his guidance, Portal has forged strategic partnerships with leading pharmaceutical companies, including Takeda and Sanofi, to integrate its cutting-edge technology into their combination products. He has successfully raised over US$60 million (£45 million) in venture capital and non-dilutive funding, propelling Portal's growth. Dr Anquetil holds a PhD in Bio-Instrumentation from the Massachusetts Institute of Technology (Cambridge, MA, US), an MBA from Harvard Business School (Boston, MA, US), and a Master's degree from ETH Zurich (Switzerland) and the University of Tokyo (Japan). His research has been published in peer-reviewed journals and featured in prominent outlets such as MIT Technology Review, Wired, PBS and CNBC.

"ITS CLOSED-LOOP CONTROL, ON-DEMAND POWER AND PRECISELY TAILORED INJECTION PROFILE ARE ALL DRIVEN BY SOFTWARE. THAT'S WHAT MAKES PRIME NEXUS FUNDAMENTALLY DIFFERENT – AND UNIQUELY SUITED TO THE INDUSTRY'S MOVE BEYOND 2 mL BIOLOGICS."

Then there's the problem of injection time. If you have a 1 mL injection, it's typically finished within a few seconds. Go up to 2 mL and it becomes harder to complete in under 10 seconds. Go beyond that, up to a 5 mL injection, and you're pushing above 30 seconds, or even up to a minute. That's a long time for an injection,

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so how do you make sure that the patient doesn't get confused and make an error during that hold time?

Historically, when targeting larger volumes, the industry has looked towards on-body devices. However, those have proven more challenging than anticipated to successfully bring to market. There are some beautifully engineered on-body solutions on the market that work perfectly – the problem is that patients don't like them. It turns out that patients don't want to stick a drug delivery device to their bodies; they'd much prefer a straightforward injection that they can administer and then move on with their lives.

But, while spring-based devices are amazing, they simply do not scale beyond 2 mL, let alone 3 or 5 mL. There's a clear demand for these larger-volume injections, but spring-based platforms are struggling to meet it. So how do you square that circle? What we've realised is that our electromechanical, software-based system is ideally positioned to answer this unmet need. Relative to a spring, it has almost unlimited, on-demand power and through closed-loop feedback control, that power can be channelled into a delivery time that is precisely met.

Q Can you expand on Portal's platform technology a little – what can PRIME NEXUS do that similar drug delivery technologies fundamentally cannot?

A There can be a misconception that software is unnecessarily complicated or expensive. This simply isn't the case – it's efficient, it's reliable and, from an engineering perspective, it's physically small. PRIME NEXUS works via a linear electromechanical actuator that pushes the plunger, all controlled using an ARM processor, much like you'd find in an iPhone (Figure 1). The software monitors the injection in real time as it happens, which gives us active control on how the drug is delivered from start to finish.

As a practical example, let's say you've got a daily injection that's kept in the fridge. If you forget to take it out of the fridge on time and don't let it warm up to room temperature, the viscosity is going to be higher than the device was intended for. A spring-based system is not going to be able to adapt. With PRIME NEXUS, because of that active control, the software can tell that it's pushing against a much harder force than expected and adjusts the motor's output accordingly in a few milliseconds; the patient will not even notice the difference.



Figure 1: Portal Instruments' PRIME NEXUS software-driven autoinjector platform.

The injection duration precision of PRIME NEXUS is about ±0.03 seconds, regardless of the viscosity, which is astounding. For pharma partners, the platform is highly adaptive to the drug – you don't have to redesign the whole device, the software can handle most of the necessary adjustments for that new drug (Figure 2). This means that the same platform can be deployed across a wide variety of drugs within a pipeline.

With a spring-based device, you have to design it, you have to make it, you have to verify it and then you have to scale it; it can take months to adapt a platform to a new formulation. With PRIME NEXUS, typically, we don't have to change anything in



Figure 2: PRIME NEXUS is highly adaptable to a wide range of APIs and formulations without needing to redesign the device each time.

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the code at all, and if we do it's usually done in only a matter of minutes, not months. What that means is that PRIME NEXUS is readily available when the drug's ready, which is the exact opposite of the way things have been done historically.

It's hard to overstate how impactful this is. It's the difference between driving a car with cruise control, where software automatically modulates the engine to keep you driving at a constant speed, and driving a car with the gas pedal fixed in place, where you've got a set amount of power and your speed is at the mercy of the road conditions. That's the difference between PRIME NEXUS and a spring-based system.

The opposite is also true – if the resistance suddenly drops because the patient has removed the injector early or activated it by mistake, PRIME NEXUS can just stop the plunger so that you don't have drug squirting out into open air and it could also tell you how much of the dose was not delivered. I think this is a real pain point for spring-based devices; once they're launched, there's no way for them to stop. A software-based electromechanical system just gives you so much more precision, control and reactivity than is possible with springs.

Q How does an electromechanical device fit into the industry's push towards sustainability?

A Sustainability is obviously of key importance to the industry, but I think this question is backwards, in a way. Today, the industry standard is the single-use disposable autoinjector. Few could have predicted just how successful these devices would become, particularly with the extraordinary rise of glucagon-like peptide-1 therapies over the past few years. I think that, right now, there are around 300 million devices being used per year, and I've seen a forecast that it could be up to a billion devices per year by 2030. These are single-use devices: you use it once and then you discard it. That's the big sustainability challenge for the industry right now – that's a huge amount of money and material to throw away.

From our perspective, a platform like PRIME NEXUS, where the bulk of the device is reusable and it's just the cartridge that's disposable is more sustainable than throwing out a whole autoinjector every time you inject. And, so far, the feedback from pharma has been extremely receptive, in Europe in particular. Of course, it's not the singular feature that would convince them to work with us, but it's an important one.

"WHAT THAT MEANS IS THAT PRIME NEXUS IS READILY AVAILABLE WHEN THE DRUG'S READY, WHICH IS THE EXACT OPPOSITE OF THE WAY THINGS HAVE BEEN DONE HISTORICALLY."

Sustainability is a bit like connectivity – it's increasingly expected, but it's rarely the primary reason a pharmaceutical company chooses a delivery platform. Their first question is always, "What can your device do for my drug?" For us, the answer is enabling the reliable delivery of larger, more complex biologics in the 5–10 mL range. That's what grabs their attention. And then you let it build from there, "Can you also do 2 mL?", "Can you offer connectivity?", "What about sustainability?". Ultimately, everything needs to serve the drug and the patient as part of a full package.

Q Given that pharma is a naturally conservative industry, why would they adopt such a fundamentally different platform?

A In my view, the pharma industry isn't averse to new technology; it regularly adopts new technology when it clearly meets an unmet need. It's a sort of "if it's not broken, don't fix it" mentality, so if something is broken, pharma is more than ready to fix it. It's what they do on the molecule side day in, day out. Pharma has demonstrated that they're ready to invest billions of dollars in incredibly complex biology if it solves an unmet need. I think it's the same thing with drug delivery devices as well.

With that in mind, we've made it our philosophy to be the easiest company to work with. We're complementary to the pharma companies we work with, so we need to have an attitude where we try to help them solve their unmet needs as best we can.

How do you convince a pharma company to work with you? In short: data. We do feasibility studies, we give them devices, we let them generate data with their own formulation or we let them send their formulations to us and we generate the data. Then, ultimately, when they see the results, they've got strong evidence that PRIME NEXUS works, that it does what it's advertised to do and that it's truly a different type of injection. And, based on the reception we've received from the pharma industry, this approach works. All our feasibility studies have been 100% successful.

Q What stage has Portal reached in its development and partnership talks with pharma?

A Earlier this year, we announced a co-development partnership we've entered into with a biotech company to deploy the NEXUS platform as the delivery device for several of their assets. We're also working with a second company, which hasn't been announced yet. We expect to be able to share more details later on this year.

In many ways, PRIME NEXUS feels like an overnight success that took 10 years. Underneath, the device is fundamentally the same architecture that we started working

"WE'RE COMPLEMENTARY TO THE PHARMA COMPANIES WE WORK WITH, SO WE NEED TO HAVE AN ATTITUDE WHERE WE TRY TO HELP THEM SOLVE THEIR UNMET NEEDS AS BEST WE CAN."

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on back in our needle-free beginnings. But, believe it or not, it's only been around 18 months since we've pivoted our technology to its current iteration, so it simultaneously feels brand new and deeply familiar.

Our next milestone is to get into the clinic with our pharma partners with a drug-device combination product. That will happen next year; we're working very, very hard to make both projects clinic-ready. Then, next year, we'll have the first IND submission with PRIME NEXUS where the drug and device will actually be combined in human trials. We're very excited about that.

Q What type of team does it take to solve a problem at the intersection of software, engineering and pharma?

A Unsurprisingly, it's a multidisciplinary endeavour, so we need people who are at the intersection of software, robotics, mechanical engineering, electronic engineering, pharmaceutical science and bioengineering. It's quite the array of skills, so we had to assemble a diverse team. I think what's interesting is that you also have to foster a culture that can support that sort of team – you need a culture where people are driven by innovation but are also open-minded. You need everyone to understand that no single person can know everything.

That philosophy of collegiality is then something we extend to our partners. When we work with a pharma company, our team will embed themselves with our pharma colleagues. Their drugs become our drug. Their patients become our patients. And that passion is genuinely shared because we see the device as an extension of the drug.



Figure 3: Attention has been paid to PRIME NEXUS's aesthetics to make it welcome in patients' homes.

Q What does PRIME NEXUS change for patients?

A For us, the best analogy is the electric toothbrush. If you've ever used an electric toothbrush, you'll know that it does a better job than just brushing your teeth manually. And, over time, brushing our teeth becomes a habit; we don't really think about it. That's how we see drug delivery devices. I take the NEXUS device home and pretend that I'm a patient; I try to see where the device would live in my house and so on. That's part of why we've put so much effort into ensuring that PRIME NEXUS is aesthetically pleasing, as it will live in the patient's home and therefore has to look good (Figure 3).

I also think that, in the future, connectivity will be a standard feature of drug delivery devices. It could be very basic, such as simply recording injection data and delivering alerts, although I think we'll come to expect some more advanced features, such as artificial intelligence-powered pattern identification. Having that data readily available could be transformative for the relationship between physicians and patients, allowing for much more direct and productive conversations. That's something that we can enable with PRIME NEXUS.

IN WHICH ISSUES COULD YOUR COMPANY APPEAR?

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Of course, for connectivity to be cost-effective, it has to be on a reusable device, which brings us back to sustainability. I think that there's a real appetite among patients for more sustainable alternatives to their current treatments, especially for reusable devices – they're intuitively less damaging to the planet. Combined with electromechanical usability and connectivity, sustainability is the third pillar that we're building PRIME NEXUS on.

Q With the autumn conference season set to start, can you give our readers a rundown of where Portal will be over the coming months?

A We're aiming to be at all the major conferences this season, including CPHI, PDA Universe, PODD and DDF. We're also doing a number of meetings in September as a bit of a push ahead of conference season. We're keen to get together with both new potential partners and long-standing collaborators and have some genuinely productive conversations.

One of the great things about conference season is getting to catch up with partners in person. I mentioned earlier that we've got two biopharma partners, but we also work with other great companies across the industry for various aspects where we don't have the expertise in-house. For example, we work with Insight (Chicago, IL, US) on our human factors work and device testing, and we're also working with some very well-established companies such as Gerresheimer (Düsseldorf, Germany) to make sure we're prepared for commercial-scale production when the time comes (Figure 4).



Figure 4: Portal has partnered with established players in the industry for human factors, device testing and commercial readiness.

"IT'S THE MULTIPLE FEASIBILITY STUDIES THAT WE'VE DONE THAT HAVE BEEN 100% SUCCESSFUL, AND IT'S THOSE EARLY CO-DEVELOPMENT DEALS THAT WE'VE ENTERED INTO. I WANT TO EMPHASISE THAT THIS ISN'T JUST FLUFF AND COOL TECH THAT DOESN'T SCALE; WE ARE ON AN INDUSTRIAL PATH WITH PRIME NEXUS."

Q Is there a final key takeaway you'd like to give to our readers?

A In our industry, there are a lot of promises and generalisations being made, so I think it's only natural to ask "is it real or is it not real?". If there's one thing I want your readers to take away from this interview, it's that the unmet need here is very real – 5 and 10 mL injections – pharma needs it.

Today, there isn't an ideal solution for this emerging class of therapies. You can administer them intravenously, but there's a strong industry-wide push to move treatment into the home whenever possible. You can split the dose into multiple injections, but that adds complexity and cost, and often reduces patient convenience. On-body delivery systems are an excellent solution for very large volumes, but for the 5–10 mL range they can be more device than the application requires. That's where we see a clear unmet need.

I think we've got a great solution for it. What's the evidence for that? It's the multiple feasibility studies that we've done that have been 100% successful, and it's those early co-development deals that we've entered into. I want to emphasise that this isn't just fluff and cool tech that doesn't scale; we are on an industrial path with PRIME NEXUS.

Of course, we cannot do it alone, so we're always ready to welcome new partners with open arms. We'd love to interact with your readers and the wider industry to find ways to work together to reach the goal of enabling those larger-volume injections that pharma genuinely needs.

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QUANTIFYING THE PHYSICAL CAPABILITIES OF FEMALE AUTOINJECTOR USERS

Dr Niels Christian Nilsson and **Dr Horacio Pace-Bedetti** of Novo Nordisk, along with **James Hoare** and **Matt Hill** of Crux Product Design, summarise a recent empirical study characterising the physical strength of female autoinjector users, which can be used as a basis for design specifications and help to ensure more accessible shield-activated autoinjectors.[1]

Shield-activated autoinjectors, including two-step autoinjectors such as YpsoMate® (Ypsomed, Burgdorf, Switzerland) and Molly® (SHL Medical, Zug, Switzerland), are widely used for the subcutaneous self-administration of medications across a range of acute and chronic indications. Users activate injections by pushing the device against the skin, thereby depressing the needle shield, which hides and shields the needle before and after injections.

Despite this apparent simplicity, successful use of shield-activated autoinjectors depends on the user's ability to apply sufficient force to activate the injection and to keep the shield depressed until the full dose is delivered. That is, users must apply sufficient activation and hold force. Force-related design outputs are therefore critical to safe and effective use. Regulatory guidance stipulates that force specifications, including activation force, must be defined, justified and validated using appropriate evidence.[2] Specifically, it is recommended that most medical devices – at minimum – should accommodate fifth percentile females in regard to physical strength.[3]

ANSI/AAMI HE75 and other human factors standards present a wealth of data characterising human physical capabilities.[3] However, these estimates are often derived from samples of healthy adult males performing generic strength tasks involving postures and movements that are similar, but not identical, to how autoinjectors are operated. As such, a gap remains between available normative strength data and the device-specific evidence expected by regulators.

"RECENT EMPIRICAL WORK HAS BEGUN TO ADDRESS THIS GAP BY QUANTIFYING THE FORCES THAT USERS EXERT WHEN SIMULATING INJECTIONS USING SHIELD-ACTIVATED AUTOINJECTORS OR SURROGATE DEVICES WITH SIMILAR FORM FACTORS."



Figure 1: User interacting with the surrogate device.

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Recent empirical work has begun to address this gap by quantifying the forces that users exert when simulating injections using shield-activated autoinjectors or surrogate devices with similar form factors.[4,5] The study summarised here contributes to this emerging body of evidence by estimating how much force young adolescent, adult and elderly female users can exert when activating shield-activated autoinjectors and when holding the device against the skin during the injection across different injection sites and grip types.[1]

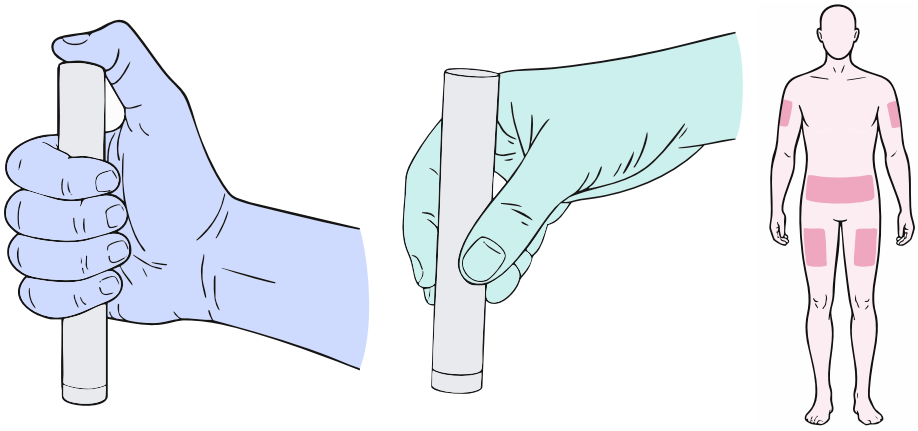


Figure 2: Illustration of power grip (left), precision grip (middle) and the three injection sites (right).

PARTICIPANTS AND METHODS

To provide a more detailed understanding of female force capabilities during autoinjector use, Novo Nordisk designed an anthropometric study and engaged Crux Product Design, who developed the surrogate devices and data-capture software, conducted the study and extracted summary statistics.

A total of 123 female participants were recruited and stratified into three age groups: young adolescents (10–12 years), adults (18–64 years) and elderly (65 years or older) users, with the latter group including participants with age-related physical impairments representative of the general population. This stratification was intended to capture the range of physical capabilities expected among intended users, with particular emphasis on less physically capable cohorts.

Participants performed simulated injections while seated, using a needle-free surrogate device with a form factor resembling common shield-activated autoinjectors (Figure 1). The surrogate device was fitted with sensors that captured force data while participants simulated injections by applying force to an injection pad. Two grip types were evaluated:

- Power grip, in which the user grasps the device firmly with the thumb placed on the end
- Precision grip, involving a three-finger pinch.

These grip types were selected because they represent foreseeable handling strategies that afford different force-generating potential.[3] The simulated injections were performed at three injection sites: abdomen, thigh and upper arm. While the abdomen and thigh are the most common self-injection sites, the upper arm was included because it appears in some instructions for use and requires a more constrained posture. For each grip type and injection site combination, participants were instructed to apply as much force as possible without hurting themselves for 25 seconds. Figure 2 illustrates the two grip types and the three injection sites.

Force-time data were recorded continuously, and two primary metrics were extracted from the force-time data for each trial (Figure 3):

- Maximum force represents the peak force achieved during each trial and serves as a proxy for activation force capability
- Mean force at fixed intervals represents the force that users can sustain over time and serves as a proxy for hold force capability.

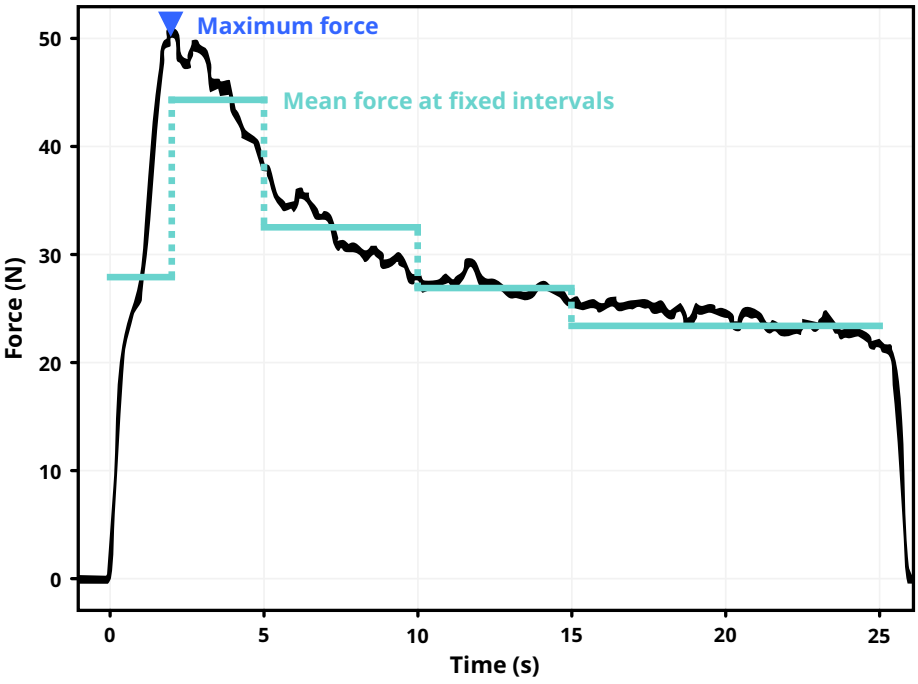


Figure 3: Simplified illustration of a force-time curve from a single trial and the two metrics extracted from the data (maximum force and mean force at fixed intervals).

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Power Grip (N)

	Adolescents			Adults			Elderly		
	Abdomen	Thigh	Upper arm	Abdomen	Thigh	Upper arm	Abdomen	Thigh	Upper arm
n	39	40	39	42	42	42	41	41	41
M	36.3	44.9	38.4	47.1	54.5	50.1	40.3	42.9	40.6
SD	10.9	15.8	15.4	13.0	15.1	13.9	13.4	13.2	15.8
P_{95}	56.6	70.0	56.6	66.3	72.0	73.2	69.2	69.4	67.4
P_{90}	50.5	60.2	50.5	64.6	70.4	66.7	61.3	60.3	65.8
P_{75}	41.1	51.5	44.6	57.6	65.4	61.3	43.6	48.0	51.9
P_{50}	35.1	42.6	38.1	45.7	54.3	51.3	39.7	40.7	37.0
P_{25}	31.5	37.5	31.6	38.2	42.1	39.1	30.0	36.4	30.0
P_{10}	25.0	26.2	20.2	29.9	36.6	30.8	26.4	29.2	24.7
P_5	14.5	21.5	18.9	25.3	30.8	30.1	25.5	21.4	16.9

Precision Grip (N)

	Adolescents			Adults			Elderly		
	Abdomen	Thigh	Upper arm	Abdomen	Thigh	Upper arm	Abdomen	Thigh	Upper arm
n	39	40	40	42	42	42	41	41	41
M	28.2	29.7	28.1	36.8	35.7	37.5	31.3	31.8	30.1
SD	9.4	8.0	8.1	8.9	9.8	9.6	9.5	10.1	10.4
P_{95}	41.1	46.6	39.8	52.1	52.9	51.0	51.8	49.6	48.5
P_{90}	39.9	38.3	37.1	48.8	48.7	48.2	41.0	45.2	45.0
P_{75}	33.7	33.3	36.0	43.1	41.3	44.6	35.3	38.4	36.1
P_{50}	26.9	29.6	26.7	36.5	35.8	39.8	29.8	29.8	27.1
P_{25}	22.3	23.4	22.4	30.1	26.7	26.9	25.9	24.1	21.4
P_{10}	15.8	21.7	17.5	25.4	24.3	25.9	22.7	22.1	18.1
P_5	14.0	16.6	16.0	23.8	23.3	22.3	17.0	19.5	16.5

Table 1: Descriptive statistics associated with maximum force in Newtons for power grip and precision grip by age group and injection site (n = sample size; M = mean; SD = standard deviation; Px = Xth percentile).

KEY FINDINGS

The study generated data describing both activation and hold force capabilities across age groups, grip types and injection sites. Summary statistics for maximum force are presented in Table 1, and percentiles related to mean force at fixed intervals are shown in Figure 4. For additional descriptive and inferential statistics, please refer to the original paper.[1] These data support an inclusive approach to defining force-related specifications by grounding upper-limit requirements in lower-percentile capabilities observed under representative handling conditions, rather than relying on anthropometric strength estimates from less representative participants and tasks.

The Effect of Age Group

Across grip types and injection sites, adult participants generally exerted higher maximum forces than both adolescents and elderly participants, as reflected in the higher mean and median values observed across conditions. At the lower end of the force distribution, adolescents often produced the lowest fifth percentile maximum forces, although differences between adolescent and elderly participants were small and inconsistent overall.

"AT THE LOWER END OF THE FORCE DISTRIBUTION, ADOLESCENTS OFTEN PRODUCED THE LOWEST FIFTH PERCENTILE MAXIMUM FORCES, ALTHOUGH DIFFERENCES BETWEEN ADOLESCENT AND ELDERLY PARTICIPANTS WERE SMALL AND INCONSISTENT OVERALL."

A similar pattern was observed for mean force at fixed intervals, with adults sustaining higher forces over time, while adolescent and elderly participants showed comparable, but more variable, force profiles.

These findings suggest that both young adolescent and elderly females represent relevant lower-bound user populations when defining activation and hold force requirements. However, the lack of a consistent difference between these groups, particularly at the lower percentiles and across sustained force application, indicates that neither group can be assumed to be uniformly less capable. From a design perspective, this supports a cautious approach in which force specifications are informed by the most conservative values observed across both populations, particularly when aiming to accommodate users operating near the lower limits of physical capability during both device activation and dose delivery.

The Effect of Grip Type

Grip type had a strong and consistent effect on force capability across age groups and injection sites. Participants exerted higher maximum forces when using a power grip compared with a precision grip – a pattern reflected across the full distribution of values. A similar effect was observed for mean force at fixed intervals, with the power grip enabling higher sustained forces throughout the injection duration. While the magnitude of this difference varied, the pattern remained evident for adolescents, adults and elderly participants alike.

These findings indicate that grip type is a key determinant of both activation and hold force capability. The consistent advantage associated with the power grip suggests that reasonably foreseeable variations in how users handle the device may meaningfully influence their ability to initiate and maintain an injection. From a design perspective, these findings indicate that instructions for use and training materials may benefit from explicitly illustrating or recommending grip types that support higher force generation, such as a power grip, particularly for users who may otherwise struggle to activate or maintain the injection.

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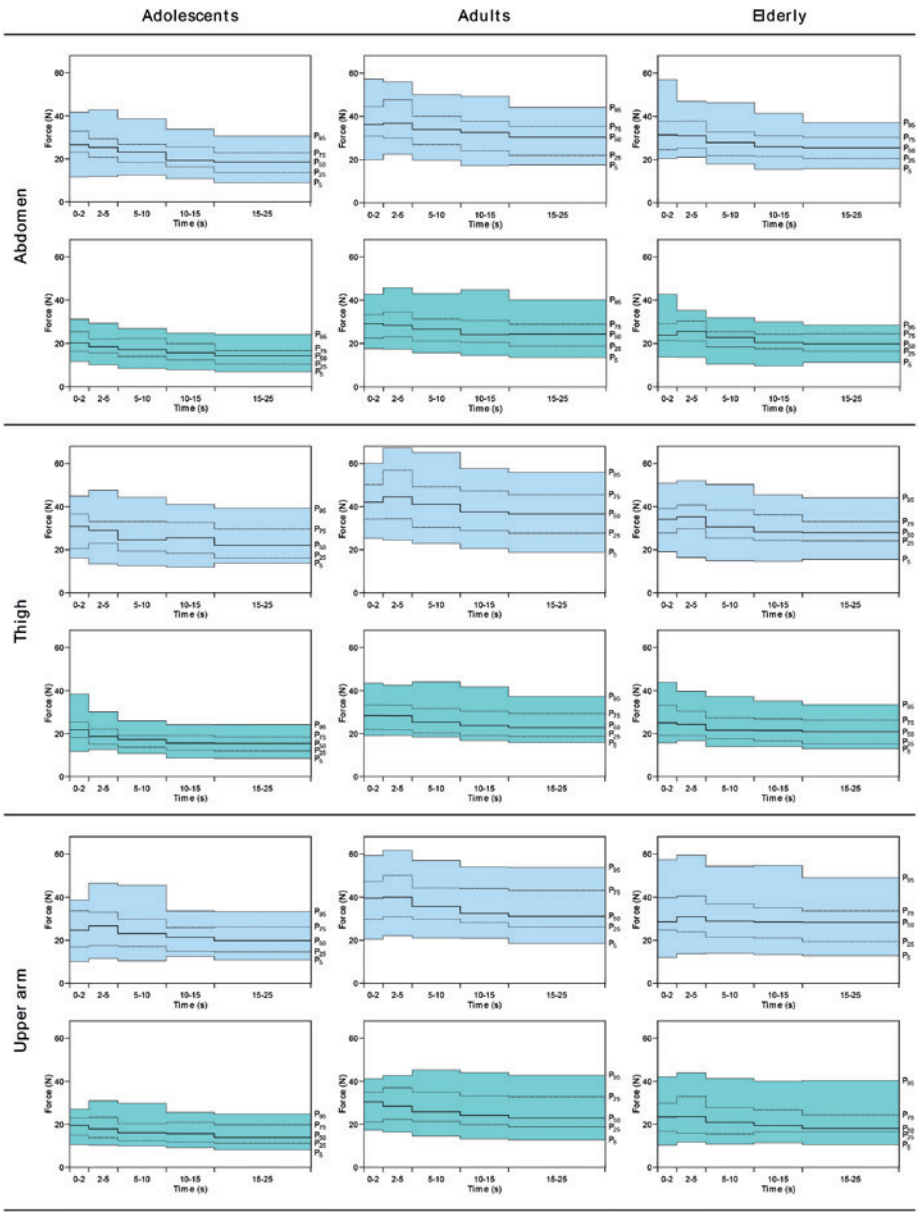


Figure 4: Percentile curves related to mean force at fixed intervals for power grip (blue) and precision grip (green) across age groups and injection site.

The Effect of Injection Site

The injection site influenced force capability primarily through its interaction with the grip type. When using a power grip, participants generally exerted higher maximum forces at the thigh compared with the abdomen and upper arm, whereas differences between injection sites were less pronounced when using a precision grip. A similar pattern was observed for mean force at fixed intervals, with thigh injections enabling higher sustained forces over time, particularly in combination with a power grip, while upper-arm injections showed lower and more stable force profiles.

These findings indicate that the injection site alone is not a primary determinant of force capability but rather contributes to performance in combination with the grip type. The observed advantage of thigh injections with a power grip suggests that certain use conditions may facilitate higher activation and hold forces, whereas more constrained positions, such as upper-arm injections, may limit force generation.

From a design perspective, this highlights the importance of considering how real-world use contexts – including injection site and handling technique – jointly influence user capability. From a labelling perspective, the interaction between injection site and grip strategy suggests that instructions for use should be mindful of how recommended injection sites may influence users' ability to apply force. Where clinically appropriate, guidance could highlight injection sites and handling approaches that facilitate more effective force application or provide additional instructions for maintaining adequate pressure when using more constrained injection sites, such as the upper arm.

CONCLUSION

This study quantified activation force and hold force capabilities for young adolescent, adult and elderly females operating shield-activated autoinjectors under different grip types and injection sites. With descriptive statistics across multiple percentiles, the study provides device-specific reference data that can inform the definition and validation of force-related specifications during autoinjector design and development.

The findings indicate that young adolescent and elderly females represent similarly relevant lower-bound user populations, that grip type is a key factor influencing both maximum and sustained force, and that the injection site affects force capability primarily in combination with grip type and posture. Taken together, these results highlight that force capability during autoinjector use is context-dependent rather than determined by a single user or device factor.

From a design perspective, this supports a cautious, evidence-based approach to defining activation and hold force requirements, grounded in representative use conditions and accounting for variability in how users interact with the device. Incorporating such context-specific data may help ensure that force specifications more accurately reflect real-world use, particularly for users operating near the limits of physical capability. In this context, a conservative approach to specification setting may involve basing upper-limit force requirements on lower-percentile capabilities observed in the least physically capable user groups under handling conditions that allow for higher

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force generation, provided that device performance and functionality are not compromised.

At the same time, it is important to recognise that such an approach may involve trade-offs between inclusivity and technical performance, and that it may not be appropriate for all device concepts or therapeutic contexts. Furthermore, where user populations are expected to include individuals with conditions that significantly impair strength or manual dexterity, additional data or population-specific adjustments may be warranted to ensure that specifications remain representative.

In parallel, the findings highlight that device labelling and instructions for use represent an important complementary lever for supporting successful use. By aligning recommended grip strategies, injection sites and handling instructions with conditions that enable users to exert sufficient force, manufacturers may help reduce use-related challenges and improve the likelihood of successful dose delivery across a diverse user population. Finally, while the presented data provide insight into both peak and sustained force capability, it should be noted that real-world force application may be influenced by factors such as comfort, effort and user preference, and that parameters such as injection time should therefore be defined based on a combination of physical capability and overall user experience considerations.

"BY ALIGNING RECOMMENDED GRIP STRATEGIES, INJECTION SITES AND HANDLING INSTRUCTIONS WITH CONDITIONS THAT ENABLE USERS TO EXERT SUFFICIENT FORCE, MANUFACTURERS MAY HELP REDUCE USE-RELATED CHALLENGES AND IMPROVE THE LIKELIHOOD OF SUCCESSFUL DOSE DELIVERY ACROSS A DIVERSE USER POPULATION."

ABOUT THE COMPANIES

Novo Nordisk is a global healthcare company founded in 1923 and headquartered in Denmark, focused on serious chronic diseases, with a strong heritage in diabetes. The company pioneers scientific breakthroughs, aiming to expand access to medicine and cure diseases. Novo Nordisk employs about 67,900 people in 80 countries and markets its products in around 170 countries.

Crux Product Design is a product development consultancy that combines technology, innovation and curiosity to develop and deploy solutions to client challenges. Its team of over 140 engineers, creative designers, usability specialists and agile project managers work together to create products and approaches that have measurable business impact.



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Expert View

FROM FRAGMENTED PROCUREMENT TO INTEGRATED ASSEMBLY: HOW THE INJECTABLE DEVICE INDUSTRY IS RETHINKING EQUIPMENT STRATEGY

Jordan Xu of DROFEN Machinery examines the shift from fragmented procurement to integrated, turnkey assembly solutions, exploring the deep technical and regulatory drivers behind this evolution as the industry increasingly recognises that the real differentiator is not the speed of individual machines but the seamless integration of the entire assembly process.

"IN A MULTI-VENDOR ASSEMBLY ENVIRONMENT, THE BURDEN OF INTEGRATION FALLS HEAVILY ON THE CDMO OR THE PHARMACEUTICAL INNOVATOR."

The pharmaceutical landscape is undergoing a profound transformation, driven largely by the explosive growth of biologics and the meteoric rise of glucagon-like peptide-1 (GLP-1) receptor agonists. With the global GLP-1 analogues market projected to reach US$268.4 billion (£198.1 billion) by 2030 at a compound annual growth rate of over 30.6%, the demand for sophisticated injectable drug delivery systems – specifically injection pens and autoinjectors – has reached unprecedented levels.[1] The clinical pipeline is equally impressive, with molecules such as semaglutide, tirzepatide, retatrutide and survodutide all progressing through late-stage development, each requiring high-volume, high-precision device assembly at commercial scale.

However, this clinical and commercial success has exposed a critical vulnerability in the manufacturing supply chain: the challenge of scaling device assembly from clinical batches to tens of millions of units annually while maintaining uncompromised precision and data integrity. The real bottleneck is no longer drug development – it is manufacturing readiness.

Historically, pharmaceutical manufacturers and CDMOs have relied on a fragmented approach to equipment procurement. A pre-assembly machine might be sourced from one vendor, the final assembly line from another and inspection or serialisation systems from a third. While this multi-vendor strategy allows companies to select what they perceive as "best-in-class" standalone machines, it introduces profound integration challenges that can delay time-to-market by, for example, 12–18 months, complicate regulatory compliance and increase the total cost of ownership.[2]

THE PITFALLS OF FRAGMENTED PROCUREMENT

In a multi-vendor assembly environment, the burden of integration falls heavily on the CDMO or the pharmaceutical innovator. When equipment is sourced from disparate suppliers, the resulting assembly line is often a patchwork of different software architectures, control philosophies and mechanical platforms. This fragmentation manifests in several critical areas that demand careful examination.

THE CHALLENGE OF UNIFYING SOFTWARE ARCHITECTURE

Modern injection pens consist of 15–25 intricate components – dosing mechanisms, clutch systems, drive sleeves, dose buttons and outer shells – requiring precise synchronisation between numerous assembly stations. When a pre-assembly line operating at 160 units per minute must feed into a final assembly line operating at 80 units per minute, the handshake between these systems must be flawless.[3]

In a fragmented line, machines often use different programmable logic controllers (PLCs). Achieving synchronisation across disparate systems requires custom middleware, protocol converters and complex programming. Each additional interface point increases the risk of communication failures, unplanned downtime and data loss. In contrast, an integrated platform uses a unified kernel framework where the overall structure of the controlling code and common components are standardised. In such advanced

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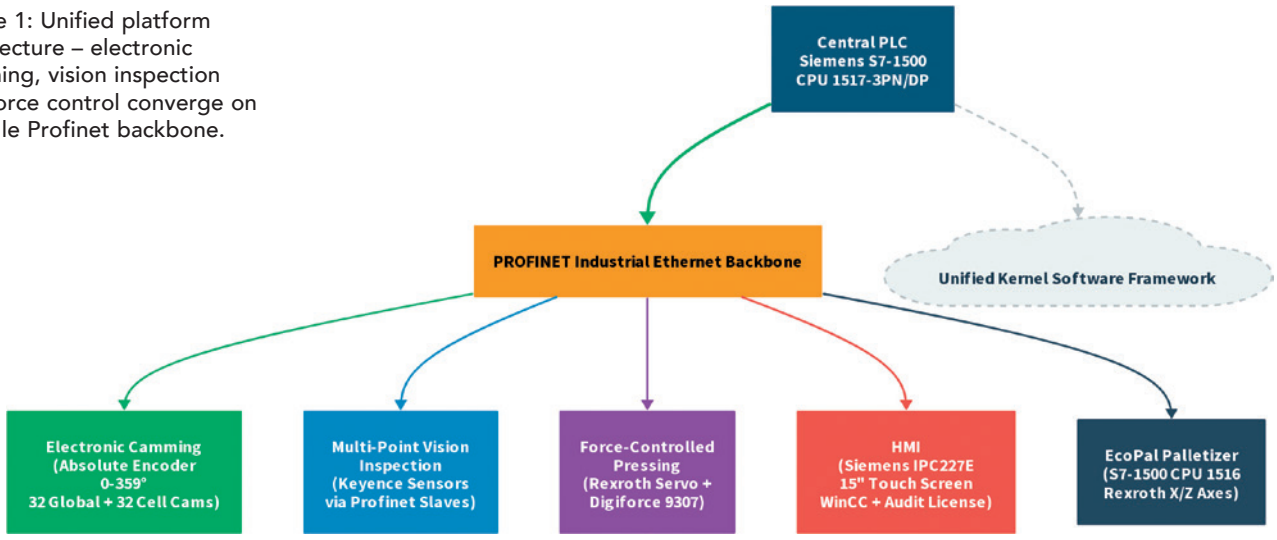


Figure 1: Unified platform architecture – electronic camming, vision inspection and force control converge on a single Profinet backbone.

architectures, specific applications – such as station initialisation, motor commands and numerical control axis functions – run seamlessly in a single, high-performance PLC environment (such as the Siemens S7-1500 CPU 1517-3PN/DP), dramatically reducing latency and integration risk.

DATA INTEGRITY AND 21 CFR PART 11 COMPLIANCE

Ensuring data integrity in compliance with Part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11), is exponentially more difficult across a fragmented line. Regulatory agencies demand comprehensive audit trails, electronic signatures and secure data logging for every critical process parameter. When multiple machines generate data in different formats and store them in isolated databases, consolidating this information into a unified batch report becomes a monumental task.[4]

Without a unified approach to 21 CFR Part 11 compliance, organisations face risks such as inconsistent audit trails, uncontrolled user access across different systems and the inability to demonstrate continuous data integrity during regulatory inspections.[5] In an integrated system, an automated audit trail feature runs automatically after the device is started. Any change made to the system – whether it is a parameter modification on a load cell device or a recipe adjustment – generates a secure entry capturing the timestamp, logged-in user, initial value, new value and a mandatory user comment. These data are securely stored at the system human-machine interface (HMI) and Line PC, preventing modification or deletion and ensuring absolute compliance and readiness for US FDA audits.

VALIDATION ALIGNMENT

The validation process – encompassing installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) – is resource-intensive. When dealing with multiple vendors, a CDMO must harmonise different IQ/OQ templates, varying interpretations of factory acceptance testing (FAT) and site acceptance testing (SAT) protocols, and distinct alarm challenge matrices. This lack of standardisation inevitably prolongs the validation timeline. What should be a six-month qualification programme can easily extend to 12 months or more, consuming engineering resources and delaying revenue generation.

THE CONVERGENCE OF ADVANCED TECHNOLOGIES ON A SINGLE PLATFORM

To address these challenges, the industry is moving towards single-platform solutions that integrate advanced technologies into a cohesive assembly system. Three key technologies are driving this convergence: electronic cam synchronisation, multi-point vision inspection and force-controlled pressing (Figure 1).

ELECTRONIC CAM SYNCHRONISATION

Traditional mechanical cams are rigid and require significant downtime for changeovers between different pen geometries. Modern integrated lines use advanced electronic camming systems. In these set-ups, an absolute encoder connected to the machine's camshaft provides the control system with a numerical value indicating the angle of rotation from 0° to 359°.

This system employs both global cams and cell cams to control system-level functions.[6] Cell cams, reserved for base machine functions such as pallet indexing and data tracking, ensure that all stations operate in perfect harmony. With a unified control logic – managed through an intuitive HMI graphical display – operators can rapidly execute changeovers between different pen designs (disposable, reusable or GLP-1 specific) while minimising the cumulative tolerance issues that plague fragmented lines.

MULTI-POINT VISION INSPECTION

As assembly speeds increase beyond 100 units per minute, manual inspection becomes physically impossible. Integrated systems embed multi-point vision inspection directly into the assembly workflow via industrial ethernet protocols such as Profinet. High-speed vision sensors, such as those made by Keyence (Osaka, Japan), are deployed at critical stations to verify component orientation, check for surface defects and confirm

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proper seating. By catching errors immediately and communicating directly with the central PLC, the system prevents defective sub-assemblies from progressing downstream, significantly reducing the final rejection rate.

FORCE-CONTROLLED PRESSING

The mechanical integrity of an injection pen dictates its dosing accuracy and user feel. Snap-fit connections, press-fits and thread engagements require precisely controlled forces. Integrated systems use servo pressing (e.g. Bosch Rexroth (Lohr am Main, Germany) linear axes) paired with precision-force monitoring units (e.g. Digiforce 9307 (Burster, Gernsbach, Germany) controllers communicating via ProfiBus). This set-up enables recording of real-time force-displacement curve at every station. As these data are captured within a unified software architecture, they can be instantly analysed against predefined tolerance windows, transforming force monitoring from a post-hoc quality check into a real-time process control mechanism (Figure 2).[7]

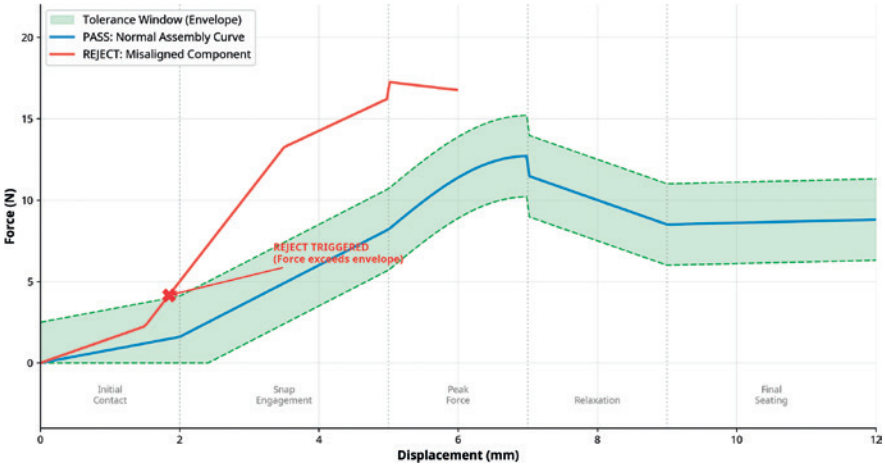


Figure 2: Force-displacement curve monitoring – real-time envelope analysis during snap-fit assembly.

THE IMPACT ON FAT AND SAT

The shift towards integrated assembly has a profound impact on the equipment qualification lifecycle, particularly during FAT and SAT – two milestones that are critical to regulatory compliance and project timelines.[8]

In a multi-vendor scenario, FAT is often conducted in silos. The pre-assembly machine is tested at Vendor A's facility, while the final assembly machine is tested at Vendor B's facility. The true test of integration – whether these machines can communicate, synchronise and produce compliant products together – only occurs during SAT at the CDMO's site. This is the worst possible time to discover compatibility issues.

Conversely, when an entire assembly line shares a common control framework provided by a single system integrator, the FAT becomes a comprehensive evaluation of the complete process. The entire line – from component feeding through pre-assembly, final assembly and end-of-line inspection – can be staged and tested as a unified system before it leaves the supplier's floor. This holistic FAT ensures that the software architecture is fully integrated, data integrity protocols generate compliant audit trails and mechanical transfer between stations operates within the specifications. Consequently, the SAT becomes a streamlined verification process, dramatically accelerating the path to commercial readiness (Figure 3).

THE POSITIONING OF LEADING SYSTEM PROVIDERS

As the demand for integrated solutions grows, equipment providers across the globe are adapting their strategies to meet this evolving market need. Established European and North American manufacturers, such as Syntegon (Stuttgart, Germany) and ATS Life Sciences (Cambridge, Canada), have long been recognised for their high-quality original equipment manufacturer machines. Syntegon offers flexible rotary and linear pen and autoinjector assembly platforms capable of outputs between 3 and 200 parts per minute.[9] ATS Life Sciences provides comprehensive automation solutions for autoinjector and pen needle assembly, with pre-configured platforms designed for lower design costs and faster delivery.[10] These companies excel at building individual machines of exceptional quality.

However, a new paradigm is emerging, championed by project-delivery system providers, particularly those based in Asia, who are positioning themselves not merely as machine builders but as holistic integration partners who take responsibility for the entire project lifecycle. They focus on filling the gap between "machine delivered" and "project ready" – a gap that has traditionally been the CDMO's problem to solve. By offering equipment supply, platform co-ordination and structured validation support – including standardised IQ/OQ templates, FAT/SAT protocols and alarm challenge matrices – they provide CDMOs with a unified turnkey solution that mitigates integration risk and accelerates time-to-market.[2,3,7]

CONCLUSION: FROM ISOLATED MACHINES TO PROJECT READINESS

The era of fragmented procurement in injectable device assembly is giving way to a more strategic, integrated approach. As the volume and complexity of therapies such as GLP-1 receptor agonists continue to rise, CDMOs and pharmaceutical innovators can no longer afford the inefficiencies and risks associated with multi-vendor assembly lines. The manufacturing readiness gap – rather than clinical success – will determine which molecules reach patients on time.

By embracing single-platform solutions that unify software architecture, ensure end-to-end data integrity and streamline the validation lifecycle, manufacturers can achieve the high-speed, high-precision assembly required to meet global demand. The future of injectable device manufacturing lies not in isolated machines, however excellent they may be individually, but in cohesive, turnkey systems that deliver true project readiness – from the first component

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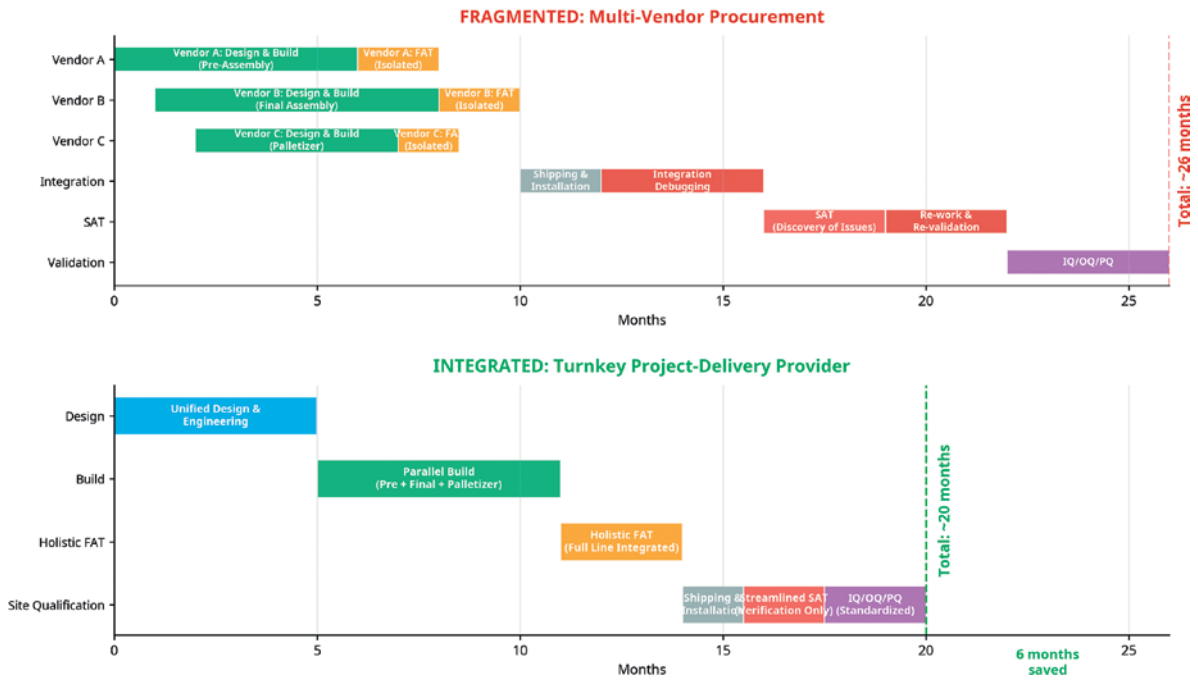


Figure 3: Fragmented versus integrated validation timeline – comparing multi-vendor FAT/SAT with turnkey holistic qualification.

fed into the line to the final validated batch released to market.

ABOUT THE COMPANY

DROFEN Machinery is a project-delivery system provider specialising in integrated assembly systems for injectable drug delivery devices. The company designs and manufactures pre-assembly and final assembly lines for injection pens, prefilled syringe filling systems, end-of-line handling and structured validation-support packages covering FAT/SAT and IQ/OQ/PQ. Its project approach combines equipment delivery, platform co-ordination and regulatory-validation support. Key capabilities include: unified Siemens S7-1500 PLC architectures with Profinet industrial ethernet, integrated 21 CFR Part 11-compliant audit trail systems (TIA WinCC with Audit Licence), electronic cam synchronisation, multi-point Keyence vision inspection, and Rexroth servo driven force-controlled pressing with Digiforce 9307 real-time monitoring.

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Expert View

CANNULA SELECTION FOR PREFILLED SYRINGE APPLICATIONS

Stephan Schatz of Jecture, along with **Dr Wenzel Novak**, discuss the considerations that go into optimising cannula selection for an injection device, including patient comfort, drug requirements, manufacturability and intended use case, arguing that the best selection will be one that successfully balances these factors rather than maximising a single parameter.

"THE OPTIMAL CANNULA DESIGN DEPENDS ON THE CONTEXT OF USE – AN EMERGENCY-USE SCENARIO REQUIRES DIFFERENT CHARACTERISTICS THAN AT-HOME USE, WHERE EASE OF USE, COMFORT AND PATIENT CONFIDENCE MAY BE MORE CRITICAL."

PAIN REDUCTION – OPTIMISING PATIENT COMFORT

The cannula is one of the most critical components of an injection system – it represents the first physical interface between the patient and the medication and therefore has a significant impact on patient comfort, confidence and overall acceptance of the therapy. As such, minimising pain is a key factor in cannula selection. Several cannula parameters contribute to the overall patient experience:

- **Low Penetration Force:** Primarily influenced by cannula tip geometry and outer diameter. A sharper, smoother tip and a smaller outer diameter generally reduce the force required to penetrate the skin.
- **Low Gliding Force Through the Skin:** Mainly influenced by surface coating and surface roughness. A smooth, polished and appropriately coated surface can reduce friction and minimise the force required during insertion.
- **Low Injection Force and Short Duration:** Primarily driven by cannula inner diameter and drug viscosity. A larger inner diameter and lower drug viscosity can reduce flow resistance, resulting in lower injection force and shorter injection times.
- **Controlled Tissue Penetration and Minimised Trauma:** Influenced by the way the cannula penetrates and opens the skin. A cutting geometry can create a cleaner skin opening than a punching mechanism and support faster wound healing.
- **High Mechanical Stability:** Primarily determined by wall thickness and tip design. Sufficient wall thickness and a robust tip design can help prevent bending, deformation or hooking during handling and insertion.
- **Best Fit for Intended Use:** Driven by the target population and specific usage scenario.

The optimal cannula design depends on the context of use – an emergency-use scenario requires different characteristics than at-home use, where ease of use, comfort and patient confidence may be more critical. Ultimately, the right combination of features determines the suitability for the intended use. The patient experience is determined by multiple interacting cannula, drug and intended use parameters. Optimising for one parameter alone is not sufficient.

DRUG REQUIREMENTS – UNDERSTAND THE DRUG

Alongside patient needs, the drug molecule defines a decision-critical set of design requirements based on its size, complexity, fragility, concentration and viscosity. The correlation between these factors is described by the Hagen-Poiseuille equation; a simplified relationship for a Newtonian liquid flowing through a cylindrical cannula:

$$\Delta P = 8\eta LQ/\pi r^4$$

- η = Viscosity
- L = Cannula length
- Q = Flow rate
- r = Internal radius.

The r^4 relationship is particularly important – a small reduction in internal diameter can cause a very large increase in pressure, and therefore injection force. Imagine 5 N of force depressing the plunger of a 1 mL syringe containing saline (η of 1.02 cP at 20°C) and with a cannula length of 25 mm. As the inner diameter of the cannula is reduced,

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the free-flow delivery time varies significantly:

- 25G cannula (0.28 mm): ~5 sec
- 27G cannula (0.21 mm): ~10 sec
- 29G cannula (0.16 mm): ~31 sec
- 31G cannula (0.14 mm): ~71 sec

It is important to note that, for needles and cannulas, the gauge (the standardised size designation) primarily refers to the outer diameter, with lower gauge numbers corresponding to larger outer diameters. However, for flow rate and injection pressure, the inner diameter is the relevant parameter, and different wall-thickness standards can be available for the same needle gauge, resulting in different inner diameters. Typical wall-thickness classifications include (Figure 1):

- Standard wall
- Thin wall
- Extra-thin wall
- Ultra-thin wall.

Therefore, a cannula should not be described by gauge alone. The wall thickness and resulting inner diameter are equally important, particularly when evaluating flow rate, injection pressure, injection time and shear forces.

For a given cannula and fluid, injection time is inversely proportional to pressure and proportional to injection length and volume. Therefore, doubling the pressure or reducing the cannula length or injection volume by half will reduce the injection time by approximately 50%. The drug viscosity is generally determined by pharmaceutical requirements, such as efficacy, stability and formulation constraints, and therefore cannot usually be adjusted to optimise injection time.

Water-based drugs can typically be delivered through a 25G or 27G cannula with relative ease; by optimising the relevant delivery parameters, a 29G cannula can also be suitable for 1 mL applications. Using thinner cannulas increases the required injection pressure and can lead to longer delivery times, potentially exceeding the "10-second rule", the commonly targeted maximum injection time to achieve complete dose delivery and patient acceptance. A 31G cannula

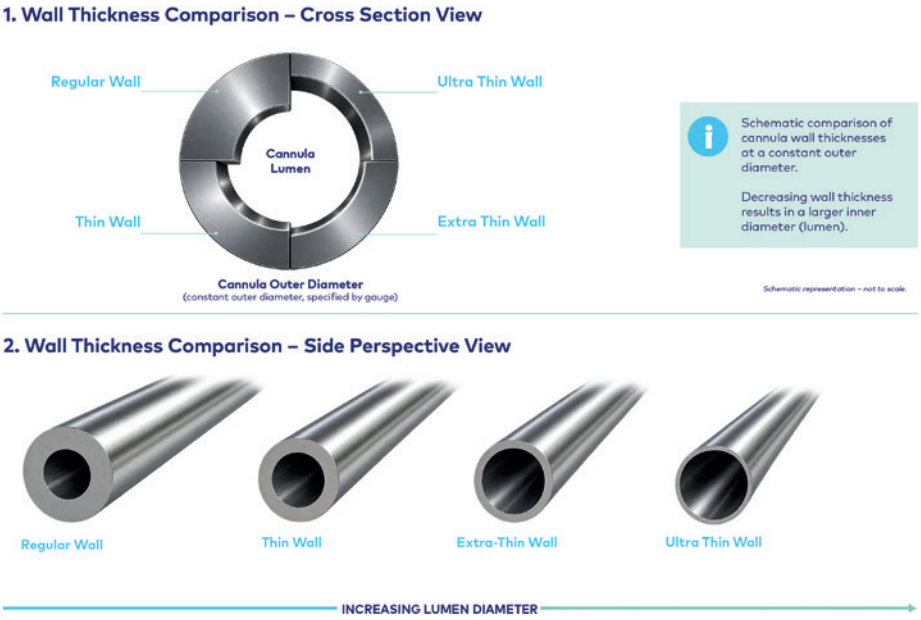


Figure 1: Influence of cannula gauge, wall thickness and cannula length on water flow resistance.

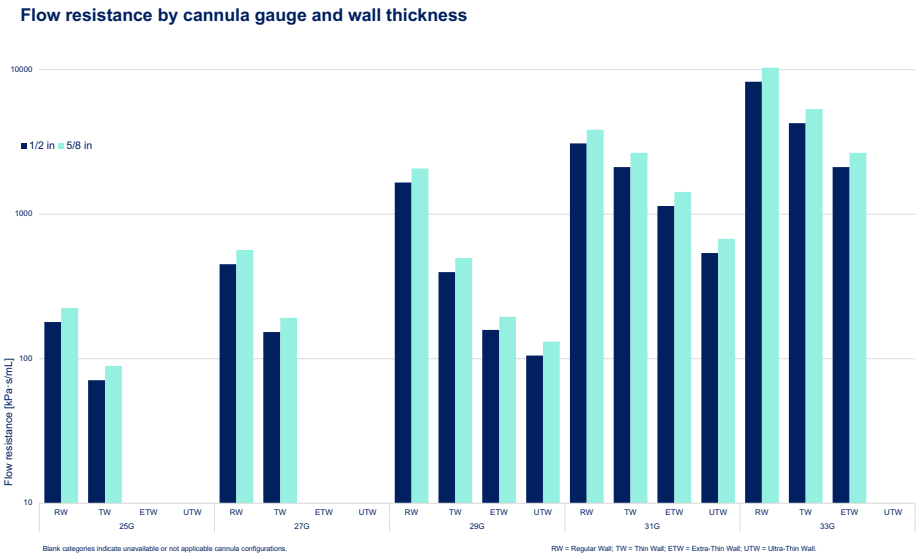


Figure 2: Increasing complexity and potential mechanical stress susceptibility of injectable drug products.

or smaller is generally more suitable for low-viscosity, low-volume applications, for the required injection force and delivery time to remain within acceptable limits (Figure 2).

Autoinjectors and injection pens can compensate for smaller cannula diameters by applying higher injection pressures, thereby reducing delivery time. However, higher injection pressure may increase the risk of pain, tissue trauma or haematoma. This is one of the key drivers behind wearable delivery systems, which enable controlled administration over longer periods and therefore allow the use of smaller cannulas while maintaining acceptable injection pressures and patient comfort.

The temperature of the drug is typically assumed to be close to room temperature. Even when a drug is taken directly from a refrigerator, the impact on viscosity and delivery performance is generally limited, although lower temperatures can still cause

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patient discomfort. Cold injections should therefore be avoided where possible by allowing the drug to reach an appropriate temperature before use.

The integrity of the drug molecule is highly relevant – the therapeutic effect depends on maintaining the molecule in its fully functional form. Small molecules are generally robust and can withstand significant mechanical stress without a relevant impact on their functionality. However, as molecular complexity increases – from proteins and monoclonal antibodies to viruses and living cells (Figure 3) – sensitivity to mechanical stress and shear forces generally increases.

The shear forces generated during drug delivery can therefore potentially impact molecular integrity, biological activity and, ultimately, the efficacy of the medication. The potential impact should be assessed and verified during formulation development and clinical/device trials, along with cannula design compatibility testing. As such, it is the drug that defines the performance requirements of the cannula.

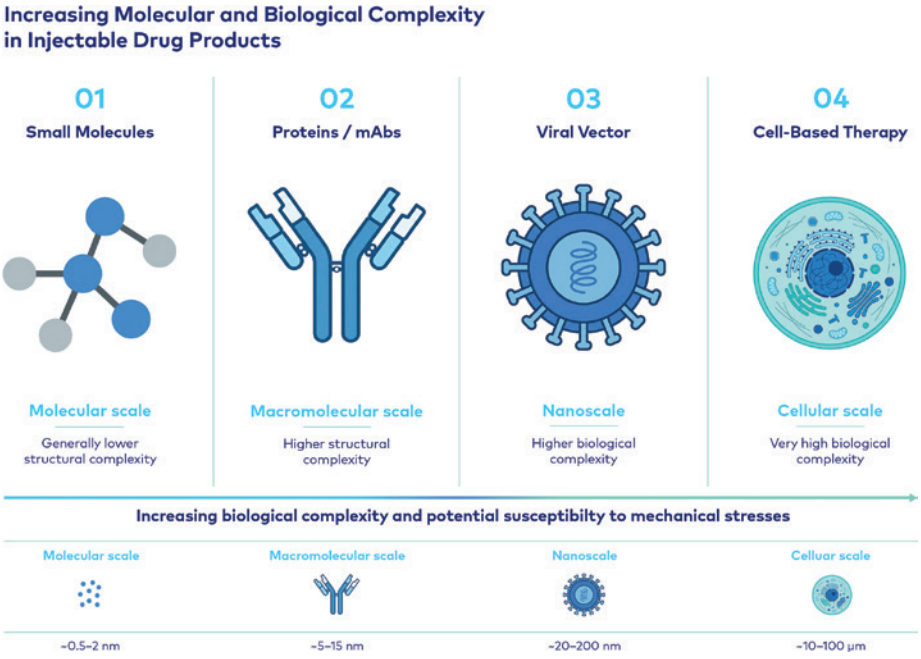


Figure 3: Effect of cannula wall thickness on lumen diameter at a constant outer diameter.

CANNULA DESIGN – TRANSLATING REQUIREMENTS INTO TECHNOLOGY

Drug stability, injection volume, acceptable application force, delivery device compatibility, minimum acceptable inner diameter and required mechanical stability define the appropriate inner and outer diameters of a cannula. For example, an extra-thin-wall cannula may provide better flow performance but could be too fragile for emergency applications.

The application environment, such as home care or emergency use, determines the critical tip requirements. For example, in a military emergency, adrenaline may need to be administered through clothing. In such a situation, a highly optimised cutting tip designed for conventional injection may not be the best solution. Tip sharpness, mechanical stability and cutting/penetration capability need to be optimised for the specific use case.

Whether the cannula is used by healthcare professionals or patients at home, whether injections are performed frequently or repeatedly at the same site, and the characteristics of the target demographic all influence the requirements for patient comfort and tissue response. For example, older patients may have reduced wound-healing capacity, making low penetration force and minimised pain particularly important for optimal wound healing. All of these requirements are ultimately translated into the physical parameters of the cannula:

- Cannula gauge
- Cannula length
- Wall thickness
- Tip geometry and bevel
- Mechanical strength and stability.

Cannula design is about optimising the complete system – not maximising a single parameter. The best solution is the one with the best overall balance, not the best individual specification.

MECHANICAL DESIGN OPTIONS – THE IMPACT OF GEOMETRY

Material Selection

AISI 304 and 316L stainless steel are the most common materials for injection cannulas. They provide a good combination of mechanical strength, corrosion resistance, manufacturability and dimensional stability, making them suitable for a broad range of intended uses. Where higher flexibility or super elasticity is required, materials such as nitinol (nickel-titanium) can be considered, although these are typically used for more specialised applications.

If material purity and control of elemental impurities are critical for the drug product or patient safety, low-cobalt or cobalt-controlled stainless steel can be selected to further reduce the proportion of cobalt in the cannula material. Ultimately, the intended use defines the necessary balance between functionality, patient safety, manufacturability and cost.

Gauge and Wall Thickness

For a cannula, wall thickness is a key parameter for mechanical stability, but it must always be considered together with the gauge and the material properties. ISO 9626:2016 describes the standard range from 10G to 34G, giving the standard inner and outer diameters and their tolerances, including definition of wall thickness. Some other diameters outside the ISO standard do exist, but diameters are always related to tube and material availability. Critically, the thinner the wall is, the greater the risk of bending or buckling – standard wall thickness is already low, so thinner walls must be handled with care (Table 1).

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Wall Classification	Wall Thickness	Inner Diameter	Relative Bending Stiffness	Critical Buckling Force
Regular wall	0.064 mm	0.209 mm	100%	1.78 N
Thin wall	0.051 mm	0.235 mm	90%	1.60 N
Ultra-thin wall	0.038 mm	0.261 mm	75%	1.34 N

Table 1: Illustrative bending and buckling statistics for a 29G needle.

"THE OPTIMAL DESIGN IS ALWAYS A COMPROMISE BETWEEN SHARPNESS, ROBUSTNESS, MANUFACTURABILITY AND THE INTENDED USE."

Tip Geometry

The tip geometry is the first point of contact with the patient and therefore has a direct impact on penetration force, tissue interaction, coring, tip stability and patient comfort. The optimal design is always a compromise between sharpness, robustness, manufacturability and the intended use.

Two standard tip geometries are 3-bevel, which is well-established, robust and cost-efficient, with a good balance between penetration performance, tip strength and manufacturability; and V-bevel, which is typical for prefilled syringes and autoinjectors, offering reduced penetration force but more controlled penetration behaviour. Beyond those two, there is a wide range of additional tip geometries that are used for specific applications and requirements, such as particular penetration conditions, blood collection, intradermal delivery and other medical applications (Figure 4).

Coring is relevant both during needle-shield assembly and during skin penetration. It describes the risk of cutting and removing small particles or plugs from the penetrated material, such as elastomeric needle-shield material or skin tissue. The geometry and sharpness of the cannula tip have a direct impact on coring – as a general rule, a very sharp front tip and sharp cutting edges, combined with a smoothly finished cannula "eye", are highly effective in minimising coring.



Figure 4: Examples of specialised cannula tip designs.

THE OPTIMAL SOLUTION FOR THE MEDICATION, THE PATIENT AND MECHANICAL STABILITY

There is no perfect cannula – the optimal design is always a carefully balanced compromise between patient comfort, drug delivery performance, mechanical stability and manufacturability. For example, a low-cost, infrequently used medication may require a very different cannula than a high-value, frequently administered or highly sensitive medication. The key factors to consider for each aim are:

- **Patient Comfort:** As small as practical, optimised sharpness, smooth surfaces and minimised coring. Enables lower penetration force, less tissue trauma and improved patient acceptance.
- **Drug Delivery Performance:** Inner diameter as large as practical, using a material with a suitable extractables and leachables profile. Enables lower injection forces and shorter delivery times while maintaining drug compatibility.
- **Manufacturability:** Standardised designs, optimised bevel geometry and standard diameters. Enables reduced manufacturing complexity, shorter cycle times and lower cost and process variability.
- **Intended Use:** The application determines the optimal combination of parameters – the design must reflect the most relevant use-case factors, such as frequency of use, drug value, injection volume, viscosity, user population, device type and required robustness.

The best cannula is not the one that maximises a single parameter – it is the one that delivers the best overall performance for the specific application. The drug delivery industry has decades of experience in developing and manufacturing cannulas and an established partner can provide the right solution for each intended use. New designs continue to minimise coring, improve patient comfort, reduce tissue

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"THE BEST CANNULA IS NOT THE ONE THAT MAXIMISES A SINGLE PARAMETER – IT IS THE ONE THAT DELIVERS THE BEST OVERALL PERFORMANCE FOR THE SPECIFIC APPLICATION."

trauma and enable billions of cannulas to be manufactured annually with consistent, reproducible quality. The technology is available – the key is to choose the right cannula.

ABOUT THE COMPANY

Jecture develops and manufactures medical cannulas and cannula systems for drug delivery and other medical applications. Its portfolio ranges from raw cannulas and assembled components to application-specific cannula systems integrating metal and plastic components. For drug delivery applications, Jecture provides solutions for prefilled syringes, autoinjectors, injection pens and other liquid drug delivery systems, as well as development and manufacturing support. The company operates manufacturing sites in Germany, Poland and Slovakia.



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A LARGE-VOLUME AND HIGH-VISCOSITY AUTOINJECTOR DELIVERY PLATFORM FOR BIOTHERAPEUTICS

Asmita Khanolkar, **Marta Vilaplana**, **Susanna White** and **Pete Evans**, all of **SMC Ltd**, present the Bios platform, designed to simplify device development for the delivery of biologics while maintaining identical key design aspects across all Bios variants.

As today's medicines evolve to include biotherapeutics, the complex delivery needs for the self-administration of high-concentration, high-viscosity and large-volume doses continue to increase. Achieving the optimal concentration for therapeutic efficacy in a patient-preferred, self-administration setting requires new device solutions for subcutaneous (SC) rapid delivery. SMC's Bios autoinjector platform solution has capability for large-volume delivery (up to 5.5 mL) and high viscosity for rapid delivery (under 30 seconds).

RAPID SC DELIVERY

Although it has been established that SC delivery of larger volumes is feasible, this has mainly been established for

"DOSE VOLUMES OF 3–5 mL IN A RAPID DELIVERY SETTING VIA AN AUTOINJECTOR CONTINUE TO REMAIN AN AREA OF DEVELOPMENT, AS THERE ARE SEVERAL CHALLENGES TO CONSIDER WHILE DEVELOPING AN AUTOINJECTOR SOLUTION FOR LARGE-VOLUME SC DELIVERY."

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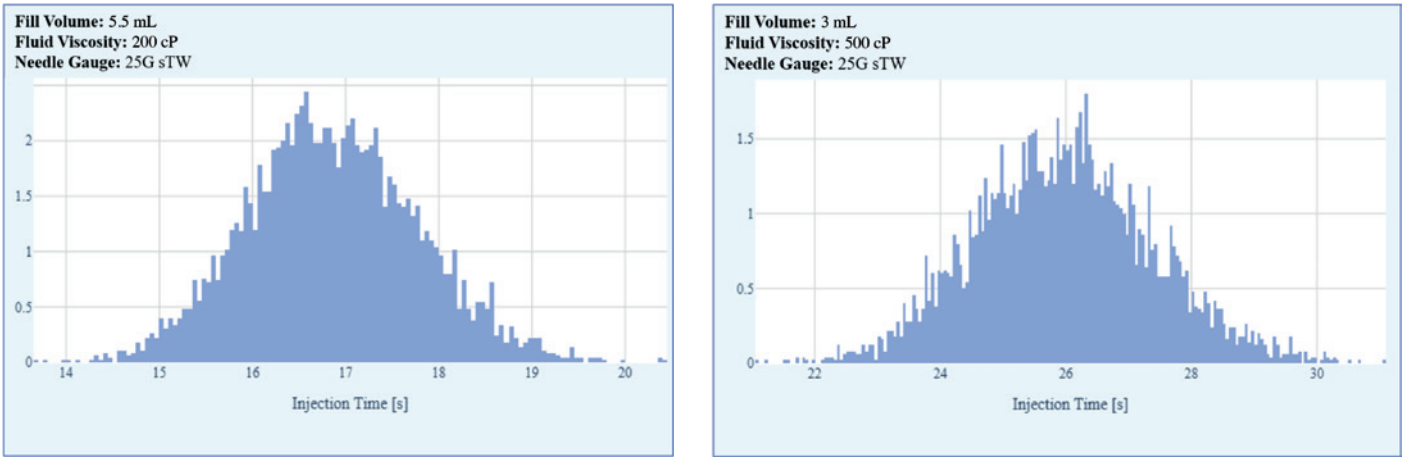


Figure 1: Delivery time evaluation with dose (fill volume), viscosities and needle sizes.

injections with longer injection times. Dose volumes of 3–5 mL in a rapid delivery setting via an autoinjector continue to remain an area of development, as there are several challenges to consider while developing an autoinjector solution for large-volume SC delivery.

Mechanical Design Limits

The power required to deliver large volumes via an autoinjector is substantially higher than for typical volumes (around 1 mL). Although high-energy springs can be used, they increase in size substantially and pose challenges for material creep limitations on components in the design. A more flexible energy source is necessary. Compressed gas as an energy source poses a better alternative to compression springs, as the energy density is sufficient to cover the design limits within a realistic size. Additionally, gas management (release and control of pressure) is predictable and consistent.

Injection forces and pressure must increase within the system to achieve rapid delivery. Most biologics use glass containers where vulnerability to fracture can limit capabilities. Staked-needle syringes offer more flexibility for ready-to-fill solutions and offer the potential to use both glass or polymeric options for syringes that can tolerate high pressure. However, in general, options are limited for high-pressure systems in currently available standard syringe containment closure system configurations.

Additionally, drug compatibility and silicone-free requirements may limit the selection even further. Luer Lock syringes may not withstand the required pressures, although they can be suitable for low-pressure applications (e.g. 5 bar). Staked-needle options are now available for glass up to 5.5 mL, although polymeric options for staked-needle syringes are not currently commercially available for large-volume applications.

Dose and Tolerability

Several factors need to be considered regarding patient tolerability with rapid injections, such as pharmacokinetics, pain, discomfort, leakages and injection site reactions. Some considerations, such as concentration, viscosity, temperature, pH, homogeneity and flow properties, are drug-related factors to be optimised. On the device side, needle selection, injection time and depth play an important role for patient tolerability. Smaller needle gauges are associated with less pain, although the speed of injection and jetting effects may potentially affect pain levels. Delivery optimisation with the injection parameters can be considered and mapped ahead of use, even in the case of suspensions or non-Newtonian formulations where the flow behaviour may be influenced by environmental factors (Figure 1).[1]

Usability

The size of the device needs to accommodate the large-dose container as well as the form factor suitable for self-administration. Autoinjectors that can provide ease of use for a large dose can improve patient adherence and device adoption. While size and form factors are an important consideration, when designing for large-volume delivery, the patient's ability to hold the autoinjector in place for the duration of injection is essential, as early removal can result in wet injections and incomplete dosing. Dexterity, vision and hearing considerations for the target population must also be considered while designing the viewing window, other audio and visual dose confirmations, and general grip and handling of the device.

"WHILE SIZE AND FORM FACTORS ARE AN IMPORTANT CONSIDERATION, WHEN DESIGNING FOR LARGE-VOLUME DELIVERY, THE PATIENT'S ABILITY TO HOLD THE AUTOINJECTOR IN PLACE FOR THE DURATION OF INJECTION IS ESSENTIAL, AS EARLY REMOVAL CAN RESULT IN WET INJECTIONS AND INCOMPLETE DOSING."

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Instructions for use and packaging require additional scrutiny for large-volume injections. In most cases, a change requiring larger-volume delivery stems from higher dose requirements, a transition from intravenous to SC delivery or a move from daily, weekly, monthly or quarterly injections (towards less frequent injections). In all these examples of large-volume SC delivery, the goal is to maintain the pharmacokinetic and pharmacodynamic profile for therapeutic efficacy while dose changes are implemented. In the case of refrigerated formulations sensitive to viscosity changes related to environmental conditions, the combination-product interactions (dose, syringe and device) must be understood as part of early feasibility studies. These help to inform the content of instructions for use and build real-use scenarios in subsequent formative studies. These are essential, as if the patient cannot use the device correctly, the dose is not delivered completely and the therapeutic effect is not achieved.

THE BIOS PLATFORM APPROACH

Delivery of biotherapeutics is challenging, as these formulations are typically delivered at high concentrations and/or high doses to achieve therapeutic effect. A balance must be struck between concentration/viscosity and volume as well as the delivery time for self-administration. Other factors to be considered for biotherapeutics are stability and shelf life. As sensitive formulations, they are prone to agglomeration and degradation. Container strength, shear forces through the needle, container compatibility and cleanliness are additional requirements for container selection. Flexibility of multiple syringe/rigid needle shield/stopper combinations and a high-energy power source are requisites for a solution to accommodate the challenging delivery requirements.

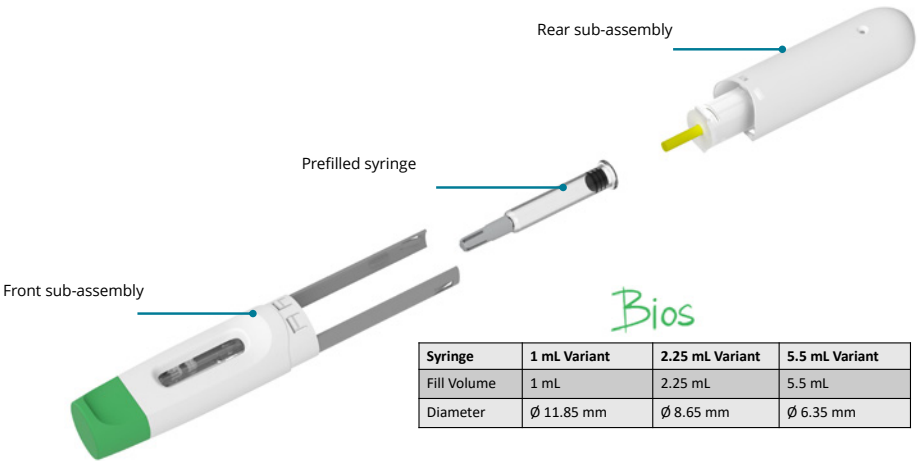


Figure 2: Bios platform configuration with 1 mL long, 2.25 & 5.5 mL ISO 11040-compliant variants.

Device Specifications	1 mL Variant	2.25 mL Variant	5.5 mL Variant
Primary Container	1 mL long	2.25 mL	5.5 mL
Delivered Volume	0.5–1 mL	1–2 mL	3–5 mL
Viscosity	Up to 1,000 cP	Up to 1,000 cP	Up to 500 cP
Staked-needle diameter	25–29G	25–29G	25–27G
Injection time target	Under 10 s, dependent on patient tolerability	Under 15 s, dependent on patient tolerability	Under 30 s, dependent on patient tolerability
Prefilled syringe shield	Rigid	Rigid	Rigid
Target needle insertion depth	~6 mm	~6 mm	~6 mm
Injection feedback	Audible and Visual	Audible and Visual	Audible and Visual

Table 1: Bios platform device specifications.

Given the challenges of large-volume delivery, a platform approach is ideal for the multiple volume, viscosity and needle requirements to consider for targeted therapies and precision medicines designed to be self-administered or delivered in a home setting. Bios is a flexible platform solution, which includes a gas-powered powerpack and accommodation of ISO 11040 staked-needle options.[2] It also accommodates the geometries of commercially available 1 mL long, 2.25 and 5.5 mL staked-needle syringes without a major change in form factor (Figure 2 & Table 1). The mechanisms defining device function and performance, as well as critical part features are the same across all Bios variants. Platform benefits include a patient-centric design, flexible and simple reconfiguration, sterilisation path options and appropriate drug contact materials. Key features include a simple two-step, one-handed operation, audible, visual and tactile feedback, along with a permanently hidden needle and passive needle safety aspects.

"GIVEN THE CHALLENGES OF LARGE-VOLUME DELIVERY, A PLATFORM APPROACH IS IDEAL FOR THE MULTIPLE VOLUME, VISCOSITY AND NEEDLE REQUIREMENTS TO CONSIDER FOR TARGETED THERAPIES AND PRECISION MEDICINES DESIGNED TO BE SELF-ADMINISTERED OR DELIVERED IN A HOME SETTING."

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The rear sub-assembly, which contains the powerpack and the activation mechanisms (including the pressure chamber and gas canister), is kept the same across all Bios configurations. The front sub-assembly holds the syringe and has change components that can hold all three different syringe sizes. Configurable prefilled syringe options with ISO 11040-compatible containers address the high-pressure requirements. A powerful gas-powered powerpack addresses delivery in acceptable injection times.

Human Factors Research

Human factors research is an integral part of development when considering a truly patient-centric approach for self-administration. Understanding and implementing patient preferences helps to ensure smooth usability of platform devices.

A 20-participant study of adults with two patient groups was completed. The first group was a mix of potential users that included both autoinjector-aware and naïve users; the second group consisted of users with manual dexterity issues. Patients with chronic diseases such as rheumatoid arthritis, Crohn's disease, multiple sclerosis and metabolic and autoimmune diseases were also included in the study. The study was successfully completed by all participants with no use errors.

Some of the human factors considerations for the Bios platform included low force to hold the device in place during injection – an especially relevant consideration for large-volume injections – device size, grip, presentation and visual and audible confirmation of injection.

Delivery Modelling

Multiple empirical studies across various larger-dose volumes and viscosities have been conducted to gather data for the Bios platform delivery model. Testing using viscosity mimics and a range of fill volumes from 0.5 to 5 mL were used to develop the model. Functional device testing was also conducted to assess cap removal, activation force, extended needle depth, dose accuracy, injection time, delivered dose and needle safety as part of the platform development. The design testing envelope covered fill volumes from 0.5 to 5 mL over a range of viscosity mimics and a range of gas pressures from 60 to 205 bar.

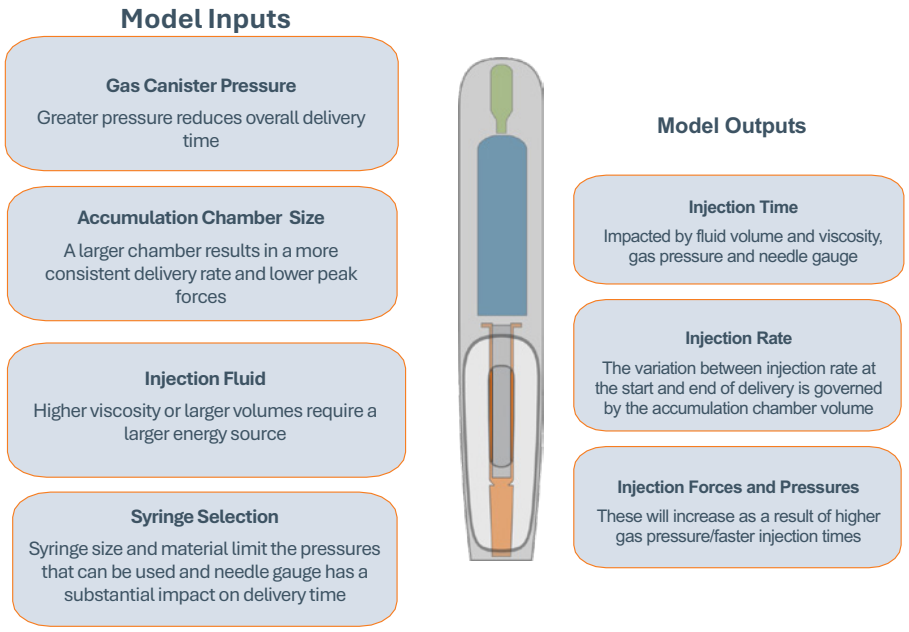


Figure 3: Model development for the Bios platform configuration.[3]

Based on empirical data, using the ideal gas law and the Hagen-Poiseuille equation framework, a mathematical model has been created for use of the Bios platform (Figure 3). Outcomes can be derived based on different input scenarios to predict injection time, delivery consistency, forces and pressures. This validated model is the foundation for understanding specific configurations of the platform design envelope – it improves

"OUTCOMES CAN BE DERIVED BASED ON DIFFERENT INPUT SCENARIOS TO PREDICT INJECTION TIME, DELIVERY CONSISTENCY, FORCES AND PRESSURES."

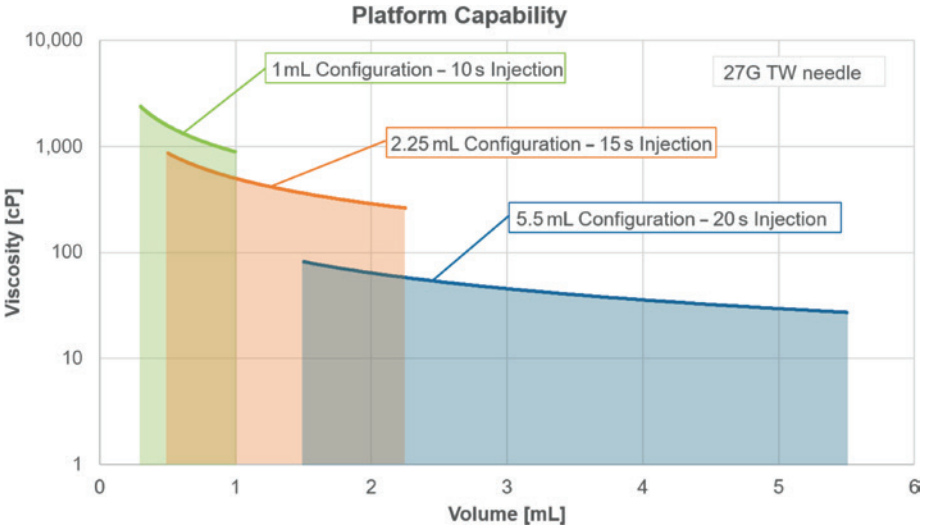


Figure 4: Bios platform delivery capability for a 27G thin-wall needle and specific target delivery times.

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the accuracy of predicted results without costly and time-consuming testing of multiple variables.

Platform Capability

The Bios platform capability covers a large range of doses and viscosities for various formulations (Figure 4). Based on the combination of product requirements, the energy source, syringe selection and syringe needle combinations can be configured to achieve optimal delivery. The device can also be manufactured to configurations for clinical and commercial volume launches.

CONCLUSION

The Bios autoinjector platform is capable of delivery of large-volume (up to 5.5 mL), high-concentration formulations, helping to provide additional options for the self-administered delivery of complex formulations to the patients that need them. The platform offers configurability of energy source, container and needle selection, thus providing freedom to optimise challenging therapeutic formulations and their delivery.

"THE BIOS AUTOINJECTOR PLATFORM IS CAPABLE OF DELIVERY OF LARGE-VOLUME (UP TO 5.5 mL), HIGH-CONCENTRATION FORMULATIONS, HELPING TO PROVIDE ADDITIONAL OPTIONS FOR SELF-ADMINISTERED DELIVERY OF COMPLEX FORMULATIONS TO THE PATIENTS THAT NEED THEM."

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Asmita Khanolkar, Senior Director at SMC Ltd has a Master's degree in Materials Science & Engineering from Worcester Polytechnic Institute in Worcester, MA, US. With over two decades of manufacturing experience specialising in the medical device and pharmaceutical industry, she has managed various device projects from concept to commercial launch. Her product portfolio includes single-use, wearable and implantable devices, drug-device, device-biologic combination products for drug delivery, biotherapeutics and pharmaceutical applications. She has held various engineering and management roles in new product development, manufacturing engineering, advanced quality planning, operations, supply chain and product life cycle management. Her current responsibilities include a corporate leadership role supporting multiple sites in early technical engagement through commercialisation for medical devices, combination products and pharmaceutical services.

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Susanna White

Susanna White is a Senior Device Development Engineer at SMC Pharma Services, with over a decade of experience in the design and test programmes for SMC's innovative autoinjector technology platforms. Much of her work has focused on the study of highly viscous and non-Newtonian drug formulations – using numerical modelling techniques in combination with experimental investigation in order to achieve the most appropriate delivery system for challenging formulations. Ms White graduated from the University of Cambridge (UK) with a Master's degree in Engineering for the Life Sciences.

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Pete Evans

Pete Evans, Director of Device Development at SMC Ltd, has been involved in the development of novel drug delivery devices for more than 25 years, working on inhalers and both pen and autoinjectors. With a career in both consultancy and industry, he has worked across all phases of development – from conception to commercialisation – for both device platforms as well as combination product developments. Mr Evans' current role is based at the SMC Ltd site in Cambridge, UK, developing innovative injection devices with the capabilities to inject the challenging drug formulations that are increasingly prevalent, due to the growth in biologics and long-acting treatments.

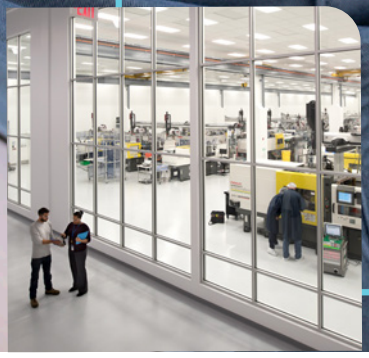
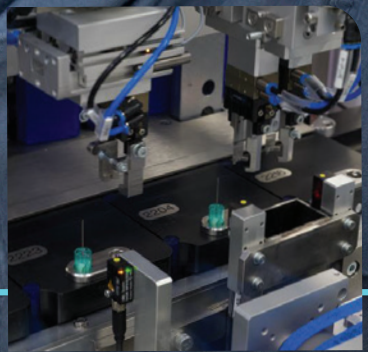
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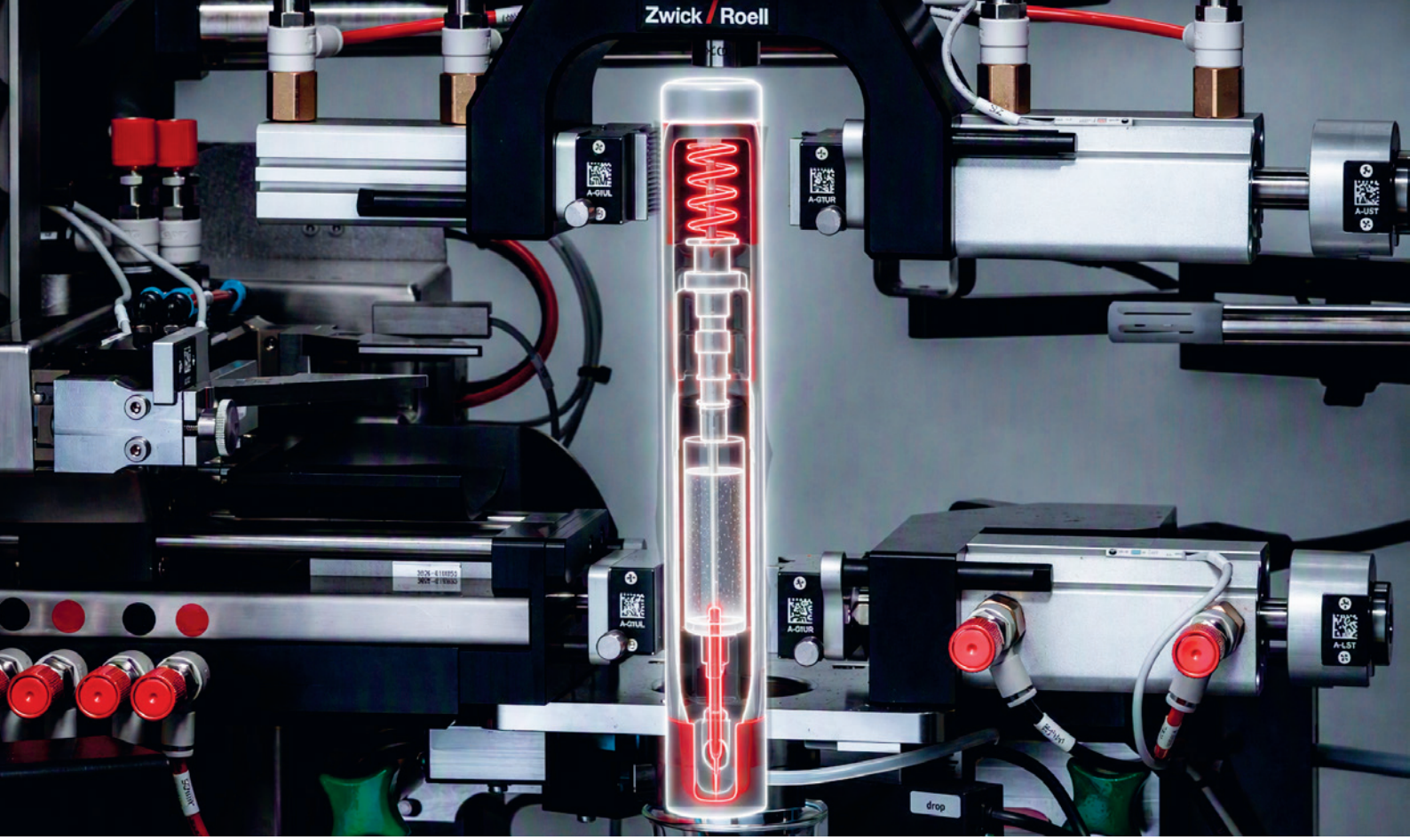
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FROM COMPONENT TESTING TO SYSTEM PERFORMANCE: THE SHIFT IN VERIFYING MODERN DRUG DELIVERY SYSTEMS

Zwick / Roell

Erik Berndt and **Peter Schmidt** of **ZwickRoell** consider the relationship between ISO and USP requirements for the effective verification of modern drug delivery systems, providing an overview linking relevant chapters of the US Pharmacopeia to the corresponding ISO-based test requirements.

Modern drug delivery systems are becoming increasingly complex. Prefilled syringes (PFSs), needle safety devices (NSDs), autoinjectors, pens and other system components must not only comply with specifications individually but also function reliably when used together. This shifts the central focus of verification – what matters is no longer simply whether a single component meets the requirements, but whether the entire system can reliably and reproducibly perform its intended function under realistic conditions of use.

This shift is particularly relevant for injection systems in which the container, API, mechanical functional unit and application scenario are closely interlinked. A PFS may comply with standards when considered in isolation, but produce different results within the overall system

> "WHAT MATTERS IS NO LONGER SIMPLY WHETHER A SINGLE COMPONENT MEETS THE REQUIREMENTS, BUT WHETHER THE ENTIRE SYSTEM CAN RELIABLY AND REPRODUCIBLY PERFORM ITS INTENDED FUNCTION UNDER REALISTIC CONDITIONS OF USE."

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when, for example, friction characteristics, spring force, trigger mechanism, drug viscosity or conditions of use interact. The testing strategy must be able to account for these interactions.

The current revision of ISO 11040-8 reflects this development. It illustrates how the industry is increasingly shifting from an isolated component-based approach towards evaluating functional system performance. The most important changes to the standard are summarised in Box 1.

BOX 1: KEY CHANGES TO ISO 11040-8:2026

- **Systems Rather than Individual Components:** PFSs are increasingly being considered in the context of NSDs, autoinjectors and other drug delivery systems.
- **Standardised Administration Time:** Administration time is evaluated as a functional performance characteristic.
- **More Statistical Design Verification:** Reliability level and confidence level are gaining importance.
- **Expanded Requirements for Leakage and Stopper Movement:** Leakage and unintended stopper movements are being examined in greater detail.
- **Greater Emphasis on Methodology and Documentation:** Standardised test procedures, statistical evaluation and traceable documentation are becoming increasingly important.

Practical Implications for Testing Laboratories: Most of the new requirements continue to be based on established force, displacement and pressure measurements. The primary changes relate to methodology, evaluation and documentation.

WHY COMPONENT TESTING ALONE IS NO LONGER SUFFICIENT

In traditional testing strategies, individual components were often evaluated separately. This approach is still necessary. However, this is no longer sufficient when the quality of an injection system is determined by the interaction of multiple components.

Particularly with modern combination products, relevant performance characteristics only emerge at the system level. These include, for example, injection time, dose delivery, activation behaviour, leakage performance and the functionality of safety mechanisms. Individual components provide only a portion of the necessary information.

System performance therefore describes not just an additional test parameter but a fundamentally different approach to verification. The test set-up, software, evaluation and documentation must be co-ordinated in such a way that reliable conclusions can be drawn about the actual performance of the entire system as a whole, while ensuring data integrity and traceability at the same time.

MECHANICAL VERIFICATION MEETS PHARMACOPOEIA REQUIREMENTS

As the focus on system-level considerations grows, mechanical testing and pharmacopoeia-related requirements are becoming increasingly intertwined. Mechanical performance evaluation, drug delivery and regulatory requirements are increasingly being considered together in development, verification and validation processes.

As a result, ISO and USP requirements are viewed less as separate sets of regulations and more as components of a common verification strategy. Linking pharmaceutical requirements to the corresponding mechanical tests creates additional transparency within complex regulatory landscapes and supports the consistent evaluation of modern drug delivery systems (Figure 1).



Figure 1: USP-ISO matrix – relevant pharmacopeial and standard requirements at a glance.

FROM TESTING SYSTEM TO MODULAR DRUG DELIVERY PLATFORM

The paradigm shift is particularly evident in the needle-based injection systems outlined in ISO 11608. With autoinjectors, pens and on-body delivery systems (OBDSs), for example, factors such as injection time, dose delivery, activation forces and the function of safety mechanisms must be evaluated. These performance characteristics arise only through the interaction of the drug, the primary container and the device technology, and therefore cannot be considered in isolation. For these applications, ZwickRoell offers a portfolio of testing solutions suitable for development, design verification and quality testing. Consistent measurement principles and evaluation algorithms ensure the comparability of test results across different testing platforms and device generations. This preserves the value of existing data and enables long-term trend analysis.

For autoinjectors, testing solutions compliant with ISO 11608-5 are available based on the ZwickRoell zwickiLine and AllroundLine testing systems. Development activities often involve frequently changing

"AS THE FOCUS ON SYSTEM-LEVEL CONSIDERATIONS GROWS, MECHANICAL TESTING AND PHARMACOPOEIA-RELATED REQUIREMENTS ARE BECOMING INCREASINGLY INTERTWINED."

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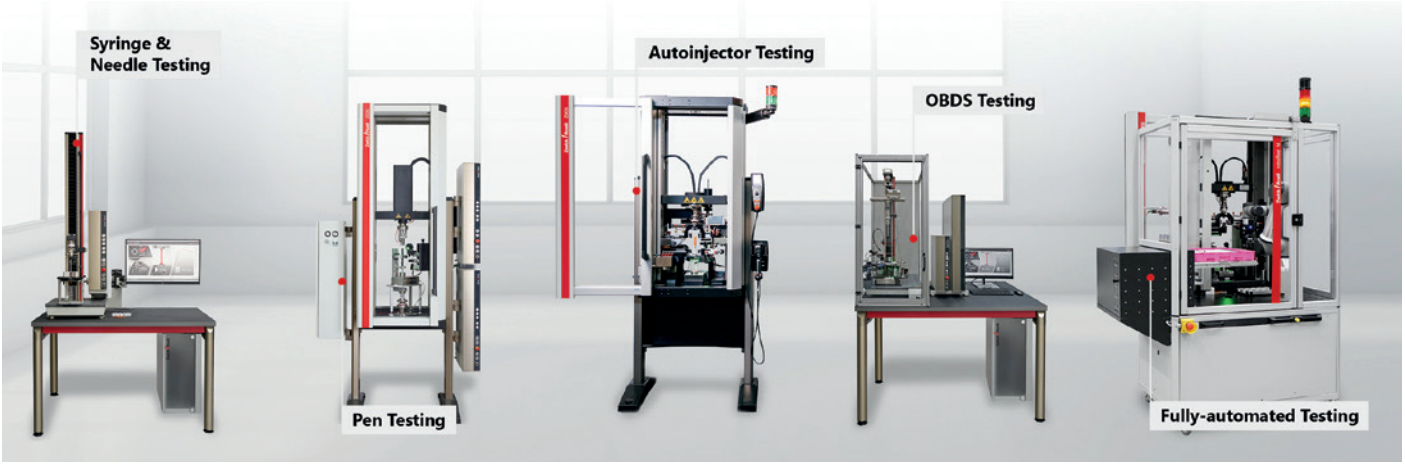


Figure 2: From syringes to autoinjectors – the right solution for every injection system.

device variants and testing requirements; the zwickiLine supports this type of application with short changeover times and the flexibility to adapt to different device generations. As a result, new concepts, variants and design changes can be evaluated efficiently.

Comprehensive development, verification and quality control tests often require combining multiple test tasks within a single platform. The AllroundLine enables different test methods – from method development and method transfer to quality control – to be implemented on a common system platform. As a result, development and verification data remain directly comparable.

A typical example of design verification is the membrane injection test, which can be used to demonstrate that the medication is administered precisely at the intended skin depth. Additional sensors, automation options and a second test area enable the combination of various test tasks within one platform. This allows for the automated testing of not only autoinjectors but also PFSs and simple pen tests – with consistent testing workflows and a common data foundation across development, verification and quality assurance.

For OBDSs, a testing solution compliant with ISO 11608-6 is available, specifically designed to meet the requirements of wearable injection devices. In addition to function testing, acoustic and visual device signals can also be evaluated. A microphone, video-synchronised recording and automated evaluation capture clicks, beeps or flashing patterns and document these events, along with the injection process, in a traceable manner. A specially developed testing technology prevents electrostatic charging and air-related influences on the API, such as crystallisation or evaporation during long injection times. In addition, adhesion force and function tests can be performed directly on the same specimen. This allows the real-world application process of an OBDS to be evaluated efficiently, reproducibly and without additional re-clamping.

For pen systems, in accordance with ISO 11608-1, the focus is on dose setting, dose delivery and torque, force and function tests. These can be combined into a seamless testing workflow using the zwickiLine and AllroundLine. Advanced configurations also enable the automatic setting of different dose levels, thereby reducing the need for manual intervention. This allows the individual functional steps of a pen system to be evaluated within a single, seamless test sequence (Figure 2).

REPRODUCIBILITY BEGINS BEFORE THE ACTUAL TEST

As system performance becomes increasingly important, the quality of the test conditions plays a decisive role. To support reliable and reproducible



Figure 3: Poka-Yoke via barcode scan – the test can only begin if the correct components are in the right place.

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testing, ZwickRoell testing systems can incorporate vision sensors, daily checks, poka-yoke principles and injector-specific interchangeable parts, depending on the configuration. Vision sensors automatically identify the correct test specimen along with its position, colour and geometry. Daily checks are standardised function tests for sensors and measuring equipment. For example, they check load cells, vision sensors, lasers, balances or microphones before the start of a test series and help detect deviations early on. This ensures that the measurement data are based on verified test conditions.

Poka-yoke describes a foolproof concept for test specimens, interchangeable parts and test programmes. Only when the correct fixture, correct test specimen and appropriate test programme have been matched is the test released. This prevents errors before testing begins, rather than detecting them only after measurement. This reduces operator errors, increases process efficiency and supports the traceability of results (Figure 3).

Injector-specific interchangeable parts are of particular importance. Injection devices such as autoinjectors and pens differ significantly in terms of geometry, material behaviour and mechanics. If unsuitable interchangeable parts are used, both the test specimen and the measurement result can be affected. Excessive gripping forces can damage the housing or components or impair the device's mechanical functions. Insufficient holding forces can cause the specimen to shift or slip out of the fixture during the test. If the force is applied to an unsuitable position, device actuation may be affected or prevented. Reproducible results therefore require an injector-specific clamping set-up.

FROM INJECTION TIME TO THE LAST DROP

Today, measuring system performance for modern injection systems requires a combination of different measurement and sensing technologies. Injection time, dose delivery, actuation forces, injection depth, click signals, visual indicators and the functionality of safety mechanisms all need to be recorded and reproducibly evaluated.

High-resolution balances, optical measurement systems and additional sensors for acoustic and visual signals are used for these tasks. Camera-based measurement systems can also be calibrated, ensuring metrological traceability and reliable measurement results. This is particularly relevant in GMP-regulated environments, as it allows the measurement to be documented and validated. At the same time, the same camera serves for both the actual measurement and subsequent documentation. Subsequent analysis is thus based precisely on the data that were also used during the measurement.

Precise gravimetric measurement methods are used to determine volume. Special collection containers reduce electrostatic charge, which could otherwise affect the measurement. This allows even small volume fluctuations to be recorded with precision. At the same time, drug dispensing is accounted for down to the last drop, which can be particularly relevant for highly viscous formulations.

PFSs AND CARTRIDGES IN A SYSTEM CONTEXT

The performance of modern drug delivery systems is based on the interaction of their components. Therefore, PFSs, cartridges, stoppers, needle systems and NSDs must not only be evaluated in terms of individual performance characteristics but also considered in the context of their subsequent function. Mechanical properties, primary containers and application systems are thus integrated within a unified testing strategy.

For testing in accordance with ISO 11040 and ISO 7886-1, ZwickRoell follows a modular approach. Rather than requiring numerous specialised test fixtures, the company's system uses a small number of universal test set-ups capable

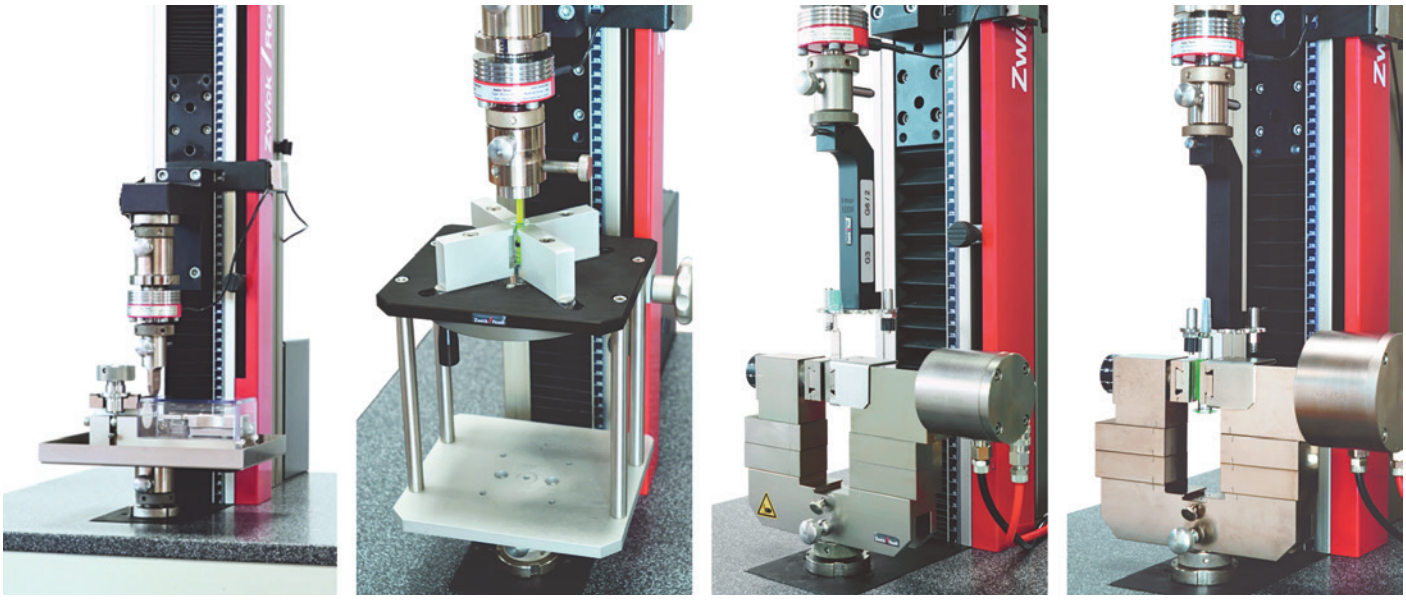


Figure 4: Selection of modular test set-ups for standards-compliant testing of relevant ISO 11040 requirements: Luer cone breakage resistance, syringe glide force, Luer lock collar pull-off force and needle shield pull-off force.

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of performing a wide range of mechanical tests. Depending on the configuration, up to ten different test methods can be implemented on a single platform. The same concept can be used for both PFSs and cartridges (Figure 4).

This is particularly relevant for syringes equipped with an NSD. Thanks to the flexibility of the second test area, the AllroundLine enables the determination of cap removal force, breakaway force, glide force and injection volume, as well as the activation and blocking force of an NSD within a single, seamless test sequence. As a result, testing is aligned more closely with real-world use conditions and less with the isolated evaluation of individual components.

SCALABLE TESTING SOLUTIONS FROM STANDARD SYSTEMS TO FULL AUTOMATION

Depending on the product phase and testing requirements, different system concepts are required: readily available standard solutions for established testing requirements, customised adaptations for specific devices or processes, and the appropriate level of automation for the required throughput.

ZwickRoell's standardised test configurations are based on years of application experience and close collaboration with customers in the medical and pharmaceutical industries. They are readily available, reliable and already proven for many common test tasks. Where standard solutions are insufficient, test set-ups can be customised or developed from scratch – for example, with specific fixtures, interchangeable parts, feeding concepts, sensor systems, software workflows or automation solutions tailored to the test specimen, process, throughput and regulatory requirements.



Figure 5: Rotary table system for high-precision testing of dose accuracy, breakaway force and glide force in syringes.

The level of automation can be selected with equal flexibility. The spectrum ranges from manual testing stations and semi-automated solutions to fully automated systems. XY tables enable the sequential testing of larger numbers of specimens with defined positioning, reduced operator influence, and quickly interchangeable magazines or racks. Rotary tables increase throughput through indexed feeding and are particularly well suited for repetitive test tasks. A balance can also be integrated to determine parameters such as dose accuracy. Robotic systems combine handling, feeding, testing and unloading within a standardised workflow, making them ideal for high-throughput applications, continuous test processes and maximum repeatability (Figures 5 & 6).

FROM TEST REQUIREMENTS TO AUDIT-READY IMPLEMENTATION

As regulatory complexity continues to increase, the challenge does not end with selecting the right testing system. Particularly in GMP-regulated environments, requirements, test methods, qualification, data integrity and audit readiness must be considered holistically from the outset. US FDA 21 CFR Part 11 requirements, such as traceability, electronic records and comprehensive documentation, are therefore becoming integral components of successful verification projects.

To support this process, ZwickRoell assists customers from the early stages of a project, for example by supplying user requirements specification templates, application consulting and pre-tests that allow test methods to be evaluated and confirmed in advance. A dedicated application laboratory enables feasibility studies, demonstrations and customer-specific testing under realistic conditions. In addition, customer training courses help users to gain confidence in test procedures, software functions and documentation requirements.

For implementation in regulated environments, ZwickRoell offers specialised qualification teams. These

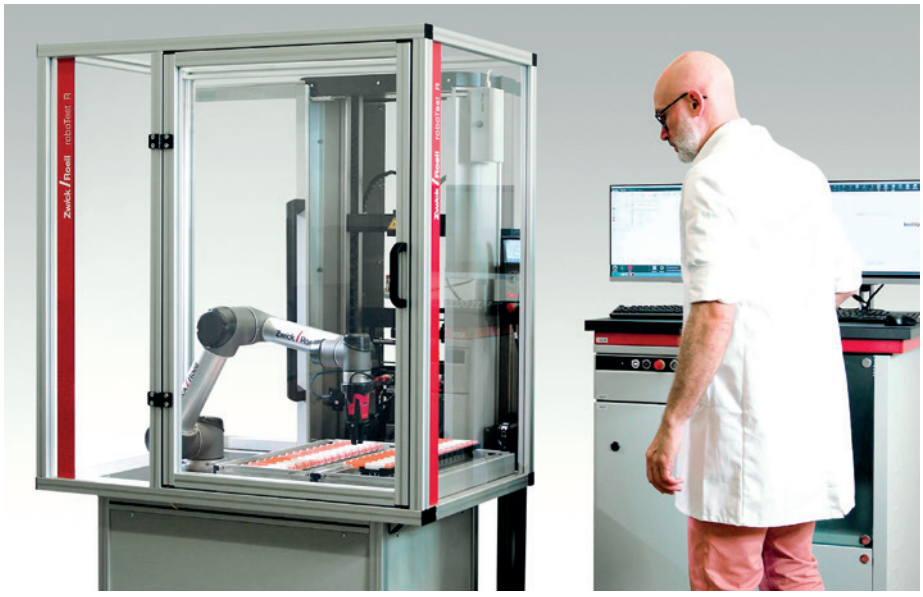


Figure 6: RoboTest N for automated function testing of autoinjectors.

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teams support projects from requirements specification through factory acceptance testing, design qualification, installation qualification, operational qualification and performance qualification support, all the way to commissioning. ZwickRoell can also provide support for subsequent modifications, machine relocations or requalifications. In addition, risk analyses, such as failure mode and effects analysis, as well as digital services and audit trails, help establish robust and audit-ready testing processes.

SYSTEM PERFORMANCE REQUIRES AN END-TO-END TESTING STRATEGY

The development of modern drug delivery systems clearly shows that evaluating individual components alone is no longer sufficient. Performance increasingly arises from the interaction between the container, the drug, the device and the application scenario.

The revision of ISO 11040-8 highlights this development, but it is only part of a larger trend. In the future, the ability to reproducibly demonstrate actual system performance under realistic conditions will be crucial.

As a result, component testing, system verification, software, automation and regulatory requirements are becoming increasingly intertwined. Successful testing strategies combine these disciplines into an integrated testing concept that equally supports development, verification and quality assurance. The challenge no longer lies solely in testing individual components in accordance with standards but in providing robust evidence of the overall system's performance throughout the entire product lifecycle. This makes it all the more important to have a partner that integrates regulatory requirements, testing technology and qualification, while supporting users throughout the entire product lifecycle. This is where the quality of modern drug delivery verification will be determined in the years to come.

"THE DEVELOPMENT OF MODERN DRUG DELIVERY SYSTEMS CLEARLY SHOWS THAT EVALUATING INDIVIDUAL COMPONENTS ALONE IS NO LONGER SUFFICIENT. PERFORMANCE INCREASINGLY ARISES ONLY FROM THE INTERACTION BETWEEN THE CONTAINER, THE DRUG, THE DEVICE AND THE APPLICATION SCENARIO."



Erik Berndt

Erik Berndt has more than 23 years of experience in materials and function testing for the medical and pharmaceutical industries. In his role as Industry Manager Medical & Pharma at ZwickRoell, he supports manufacturers of primary packaging materials and drug delivery devices with testing solutions for development, verification and quality control. Mr Berndt is an active member of several ISO and DIN committees, including ISO/TC 84, and contributes to the development of standards for drug delivery devices.

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IMPLANTABLE DRUG DELIVERY SYSTEMS: BUILDING A ROBUST SUPPLY CHAIN FROM POLYMER EXTRUDATE TO COMMERCIAL PRODUCT

Ingmar Kneer of **GAPLAST** discusses the broader considerations of commercialising an implantable drug delivery system beyond the implant itself, considering factors such as manufacturing, automation, regulatory concerns, traceability and the accompanying delivery system.

Drug-loaded implantable delivery systems are attracting increasing interest across a broad range of therapeutic areas, including ophthalmology, oncology, endocrinology, veterinary and women's health. By providing sustained and controlled release of APIs over weeks, months or even years, these systems can reduce dosing frequency, improve patient adherence and support better therapeutic outcomes.

While scientific discussions often focus on the implant itself and its release characteristics, the successful commercialisation of an implantable therapy depends on a far broader ecosystem. Implantable products are complex combination products that bring together pharmaceutical development, medical device engineering, sterilisation technologies, packaging systems and highly specialised manufacturing processes.

As regulatory expectations continue to evolve under the EU Medical Device Regulation (MDR) and pharmaceutical good manufacturing practice (GMP) requirements, manufacturers increasingly need to establish resilient, transparent and scalable supply chains capable of supporting both clinical development and global commercialisation.

THE FOUNDATION: DEVELOPING THE IMPLANT

The supply chain for an implantable therapy begins with the implant itself. Many long-acting implants use biodegradable polymer matrices that gradually degrade

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"DEMONSTRATING AND MONITORING DRUG-RELEASE CHARACTERISTICS REQUIRES SOPHISTICATED PROCESSES CAPABLE OF GENERATING RELIABLE RELEASE DATA DURING PRODUCT DEVELOPMENT, PROCESS VALIDATION AND LIFECYCLE MANAGEMENT."

in the body while controlling the release of the incorporated drug substance.

The selection of suitable raw materials is a critical success factor. Polymer characteristics, such as molecular weight, composition and degradation behaviour, directly influence the release profile of the API and, ultimately, the clinical performance of the product. Consequently, pharmaceutical-grade materials with well-defined specifications, robust quality systems and long-term supply security are essential.

In addition to material selection, significant formulation expertise is required to design an implant that can deliver the intended release kinetics. Formulation scientists must carefully optimise the composition of the extrudate and its manufacturing processes to achieve a reproducible drug-release profile throughout the intended treatment period.

It is important to note that not every API is suitable for use in an implantable drug delivery system. The implant manufacturing process itself may limit API selection. For example, thermal stability is required during extrusion or other processing steps.

Analytical capabilities are equally important. Demonstrating and monitoring drug-release characteristics requires sophisticated processes capable of generating reliable release data during product development, process validation and lifecycle management. As a result, successful implant development depends on the close interaction of material science, pharmaceutical formulation and analytical expertise.

CREATING A DRUG-DEVICE COMBINATION PRODUCT

Following manufacture of the implant, the next critical step is the integration of the drug-loaded implant with a delivery device. This stage transforms individual components into a drug-device combination product and requires the interaction of pharmaceutical and medical device manufacturing disciplines.

Assembly is typically performed on dedicated filling and assembly lines designed to meet the requirements associated with both the therapeutic product and the delivery device. Depending on the characteristics of the implant and the API, different manufacturing approaches may be selected.

One option involves assembly under controlled GMP conditions followed by terminal sterilisation, often using gamma irradiation. This strategy can offer a robust sterility assurance approach but requires all materials and components to be compatible with the sterilisation process.

Alternatively, manufacturers may adopt an aseptic manufacturing strategy. In this scenario, device components are sterilised in advance using validated methods, such as gamma irradiation or ethylene oxide, and final assembly is subsequently performed under aseptic conditions.

The chosen manufacturing route influences facility design, process validation requirements, supply-chain logistics and regulatory submissions. Consequently, effective collaboration between pharmaceutical manufacturers, device developers and sterilisation partners is essential throughout the product lifecycle.

THE ROLE OF THE APPLICATOR

While the implant itself plays a central therapeutic role, the delivery device is equally important in ensuring successful administration and overall product performance. Implant applicators must enable reliable placement of the implant into the intended tissue layer while supporting safe handling by healthcare professionals (Figure 1). Achieving these objectives can be particularly challenging, as multiple

"EFFECTIVE COLLABORATION BETWEEN PHARMACEUTICAL MANUFACTURERS, DEVICE DEVELOPERS AND STERILISATION PARTNERS IS ESSENTIAL THROUGHOUT THE PRODUCT LIFECYCLE."



Figure 1: It is crucial for implant applicators to enable safe, reliable placement of the implant into the intended tissue.

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mechanical, functional and safety-related requirements must be integrated into a compact device architecture.

One example is the implant syringe platform developed by GAPLAST (Figure 2), which incorporates several design features intended to address the practical challenges associated with subcutaneous implant administration, including:

- A retention mechanism that helps prevent the implant from unintentionally leaving the device before administration
- A viewing window that allows visual confirmation of implant presence within the device before administration
- Controlled deployment of the implant into the puncture channel, supporting placement without unnecessary trauma to the tissue, depending on implant length and application technique
- Visual confirmation of successful implantation through a visible mandrel position at the end of the application process, helping users verify that the implant has been correctly deployed
- An integrated passive needle-retraction system that automatically retracts the needle into the syringe body immediately after administration without requiring a separate activation step or additional safety shield
- A compact mechanical architecture that integrates multiple functionality and safety features within a limited device footprint.

Such functionality may appear straightforward from a user perspective, but integrating these mechanisms into a small, disposable device presents significant engineering and manufacturing challenges. Each feature must function reliably throughout the product's lifecycle and remain compatible with automated large-scale production.

FROM DEVICE DEVELOPMENT TO INDUSTRIALISATION

For implantable drug delivery systems, innovation alone is not sufficient. Successful commercialisation depends on the ability to transfer complex device concepts into robust, scalable and economically viable manufacturing processes. This challenge becomes particularly apparent for implant applicators incorporating multiple miniature components and sophisticated safety mechanisms. The manufacturing process must ensure that every device performs consistently while also meeting stringent quality and regulatory requirements.



Figure 2: GAPLAST's BiStep Precision® Implant Syringe.

To address these challenges, manufacturers are increasingly investing in advanced automation technologies. GAPLAST has recently established a dedicated automated production line in Germany for implant syringe manufacturing, along with the necessary documentation, to facilitate global commercialisation. This development reflects a broader industry trend towards the industrialisation of increasingly complex combination products. The purpose of such automation extends well beyond increasing production volumes. Advanced manufacturing systems support:

- Precise assembly of miniature mechanical components
- High levels of process repeatability and reproducibility
- Reduced need for operator intervention
- In-line process monitoring
- Automated functional and quality inspections
- Comprehensive electronic documentation of manufacturing activities
- Efficient transition from pre-serial production volumes to commercial-scale manufacturing.

For implantable drug-device combination products, such automated production concepts are becoming increasingly important for ensuring consistent quality, reliable supply and regulatory compliance.

MANAGING SPECIALISED SUPPLIERS

The supply chain for implantable therapies relies on a network of highly specialised partners contributing critical materials, components and services. These suppliers may provide pharmaceutical-grade polymers, cannulas, stainless-steel mandrels, injection-moulded components, packaging materials, sterilisation services or other critical supplies or functions. Each partner contributes directly to the overall performance and quality of the finished product.

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Needles and mandrels are particularly important examples. Their geometry, dimensional precision and surface characteristics can directly influence insertion performance, implantation accuracy and patient comfort during administration.

For this reason, manufacturers typically implement comprehensive supplier qualification programmes that include audits, incoming inspections, validation activities and continuous performance monitoring. Such processes can help to ensure consistent quality throughout the product lifecycle and support the transparency expected by modern regulatory frameworks.

TRACEABILITY AS A CORE MANUFACTURING REQUIREMENT

Under the MDR, traceability has become a central consideration for combination products. Manufacturers must maintain detailed documentation covering materials, components, manufacturing processes and quality controls throughout the product lifecycle.

For implantable therapies, this requirement is particularly important because pharmaceutical and medical device elements are combined within a single product. Effective traceability supports product investigations, post-market surveillance activities and long-term risk management.

To address these requirements, manufacturers are increasingly integrating digital traceability systems into their production environments. One example is the approach implemented by GAPLAST within its newly established automated implant syringe production line. As part of this manufacturing concept, every individual implant syringe receives a unique data matrix code. This identifier is linked to manufacturing-specific records and quality-related information, including component batches, material lots, purchased parts and production data generated during manufacturing and inspection processes, making GAPLAST's implant syringe platform a truly data-driven device.

"GAPLAST'S APPROACH ENABLES TRACEABILITY AT THE LEVEL OF THE INDIVIDUAL SYRINGE AND DEMONSTRATES HOW DIGITAL MANUFACTURING TECHNOLOGIES CAN ENHANCE TRANSPARENCY ACROSS THE SUPPLY CHAIN."

GAPLAST's approach enables traceability at the level of the individual syringe and demonstrates how digital manufacturing technologies can enhance transparency across the supply chain (Figure 3). Beyond regulatory compliance, such systems can support quality investigations, process optimisation and lifecycle management activities. Looking to the future, enabled by its data matrix code system, GAPLAST is demonstrating how next-generation implantable drug delivery systems are evolving into data-driven devices, integrating manufacturing, quality, regulatory and patient-use data across the entire product lifecycle.



Figure 3: GAPLAST's data matrix system enables traceability down to the level of an individual syringe, enabling the BiStep Precision® Implant Syringe to become a data-driven device.

FILLING, FINAL ASSEMBLY AND PACKAGING

To facilitate efficient filling of the implant syringe with the drug-loaded implant, it can be advantageous for the device manufacturer to supply the syringe to the pharmaceutical manufacturer in two pre-assembled subunits – the syringe body and the plunger unit. Under GMP-compliant conditions, the pharmaceutical manufacturer can then load the extruded implant into the depot area of the syringe body, close the device with the plunger unit, and subsequently label and package the finished syringe in accordance with the defined product requirements.

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Appropriate in-process controls should be implemented for this final assembly step in order to verify correct implant loading, closure and device integrity. In GAPLAST's system, the data matrix code applied to the device can also be linked with the relevant manufacturing and filling data, thereby extending traceability from device production through to final pharmaceutical assembly.

COMPLETING THE PRODUCT

The implant syringe represents only one component of the final commercial product. Before release, several additional elements must be incorporated into the final packaging configuration. These commonly include:

- Product labels
- Desiccant-containing systems (where required)
- Aluminium laminate barrier pouches
- Secondary packaging
- Instructions for use
- Transport and protective packaging materials.

Each component contributes to product stability, usability and regulatory compliance. As a result, packaging suppliers and contract packaging organisations form important parts of the broader supply chain for implantable therapies.

CONCLUSION

Implantable drug delivery systems represent one of the most sophisticated forms of drug-device combination products currently entering the healthcare market. While the implant itself often receives the greatest attention, successful commercialisation depends on a highly integrated supply chain that extends from polymer selection and formulation development through to device manufacturing, sterilisation, traceability and packaging.

As regulatory expectations continue to evolve under the MDR, manufacturers must ensure that product quality, patient safety and supply-chain transparency are embedded throughout the value chain. At the same time, increasing product complexity is driving greater investment in automation, digital traceability and advanced manufacturing technologies.

The recent implementation of a dedicated automated implant syringe manufacturing line and individual-syringe-level traceability by GAPLAST illustrates how the industry is addressing these challenges. Ultimately, the ability to combine pharmaceutical expertise, medical device engineering and industrialised manufacturing within a robust and transparent supply chain will be a key factor in enabling the next generation of implantable drug delivery therapies.



Ingmar Kneer

Ingmar Kneer is a Senior Sales Manager at GAPLAST and a freelance engineer specialising in plastics technology. With extensive experience as a consultant for medical devices, combination products and primary packaging, he has contributed to multiple drug-device innovations across the industry. In 2008, he initiated the development of the successful GAPLAST implant syringe, and has recently contributed to a whitepaper on the subject ("Subcutaneous implants for drug delivery: The state of the market" by GlobalData), showcasing his expertise in product development and engineering solutions.

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ASSEMBLY CONCEPTS FOR WEARABLE INJECTORS BASED ON ROI

Dr Carsten Köhler of **BBS Automation** looks at how assembly concepts drive the return on investment in the wearable injectors market and the effect of automation on these metrics.

The wearable injection device market is expanding, driven by demand for at-home therapies, chronic disease management and patient-centric care that requires convenience and adherence. The combination of miniaturisation, connectivity, and disposable or reusable form factors is driving innovation that, in conjunction with stringent regulatory and pharmacological requirements, is pushing manufacturers towards a reliable production set-up and full supply chain traceability. Accordingly, assembly processes for wearable injectors integrate precision mechanics, sterile fluid handling, electronics and controlled packaging into a seamless workflow to deliver safe and reliable drug delivery systems.

Assembly steps begin with modular subassemblies – drive mechanisms, reservoirs, needle/cannula components, adhesive patient interfaces and electronic

> "ASIDE FROM THE PRODUCTION SET-UP, ROBUST QUALITY CONTROL IS ESSENTIAL, WHETHER PAPER-BASED FOR MANUAL ASSEMBLY OR AUTOMATIC UPLOADS TO AN MES IN FULLY AUTOMATED SYSTEMS."

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modules – each inspected for dimensional tolerance, cleanliness and function before integration. Primary assembly takes place in cleanrooms, if necessary, with sterile builds executed in aseptic closed automation using robotic pick-and-place. Together with the integrated quality control via a programmable logic controller (PLC), patient safety is a top priority. Aside from the production set-up, robust quality control is essential, whether paper-based for manual assembly or automatic uploads to a manufacturing execution system (MES) in fully automated systems.

WEARABLE MEDICAL DEVICES

Wearable medical devices are body-worn technologies designed to monitor, diagnose or treat health conditions outside traditional clinical settings, including continuous glucose monitors, wearable ECG patches, ambulatory blood pressure monitors and wearable insulin pumps. These devices typically incorporate sensors that collect physiological signals (heart rate, glucose levels, activity, temperature), microprocessors for data processing, wireless modules for connectivity (Bluetooth, Wi-Fi, cellular) and user interfaces for feedback.

Wearables enable real-time monitoring and long-term trend analysis to support personalised interventions at an early stage – key applications include chronic disease management (diabetes, cardiac arrhythmias, hypertension) and medication adherence – while providing medical personnel with richer datasets and actionable information for patients.[1]

Wearable injectors are a specific subclass of these devices focused on delivering injectable drugs or biologics through the skin while being worn. Wearable injectors contain reservoirs for medication, delivery mechanisms (microfluidics, pumps, needles, microneedle arrays) and dosing control systems. Their functional modules include sterile fluid paths, precise dosing accuracy, disposable components and safety features to prevent leakage or accidental needle exposure. These devices must demonstrate both device performance and drug delivery safety, whereas monitoring wearables focus on measurement accuracy and data integrity. Key design features for wearables include comfort, usage time, data accuracy, signal artefact reduction, privacy and security of health data, and regulatory approval for medical claims.

ASSEMBLY PROCESSES

As already outlined, the many features of wearable injectors range from the fluid path and dosing mechanism to electronics with app connectivity. This leads to an assembly set-up that must facilitate a wide range of processes, including feeding of parts, screwing, glueing, ultrasonic welding, label application, electronic assembly, battery contacts and laser marking.[2] Depending on the product design, the internal features may limit the assembly steps to manual or semi-automatic assembly. Specifically, the handling of complex or unstable parts may be too complicated to automate or limit the achievable overall equipment effectiveness of the complete set-up due to unplannable stops.

Another integral part of the assembly set-up is the in-line testing of each assembly process to ensure a flawless product at the end of the assembly line. One of the most important parts is the fluid path from the reservoir or cartridge to the cannula.[3] Here, the fluid path is split between two build groups, as the cannula applicator is often a separate component from the reservoir. Another key test feature is the electronic integrity – after uploading the code onto the control board, the connectivity must be tested to ensure a stable connection with the software application. Overall, the process flow is a continuous transition from assembly to testing stations to ensure a flawless device at the end of the steps, regardless of the level of automation.

ASSEMBLY CONCEPTS

Manual Set-Up

A manual assembly set-up for wearable injectors with only essential automation requires low capital investment, offers high flexibility and quality control, and minimises human error in the most critical steps. The production area is typically a cleanroom for standard assembly operations.

When a more controlled environment is required, gowning and laminar flow hoods are installed for operations involving sterile components; workstations are used as bench-top systems with trays for build groups instead of a workflow with carriers. Most steps are executed manually and only technical essentials, such as ultrasonic welding, are automated. Visual inspections are typically performed by the operators, whereas critical functional tests are performed by automated test fixtures. Each production step is supported by fixtures to ensure the accurate placement of components. Some set-ups may use visually aided assembly with cameras and light features to enable the operator to follow the correct assembly routine (Figure 1).



Figure 1: Semi-automatic workstation.

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Semi-Automatic Installation

A semi-automatic assembly set-up targeting approximately three to five parts per minute (ppm) for wearable injectors balances the mechanisation of repetitive precision tasks with human oversight for flexibility and ease of inspection (Figure 2). The facility is organised in a linear production flow within a cleanroom; an isolator may be required for fluid path and reservoir assembly. The assembly stations are usually arranged in a linear fashion with a simplified work piece carrier set-up. The workpiece carriers can either be on a manual slide or be moved freely on a conveyor system. Component feeding mainly remains a manual process, except for difficult-to-handle parts, where a feeding system is more efficient. The assembly stations are mostly integrated into a PLC for process control and data tracking. Quality control is either performed visually by the operators or automatically within the assembly stations directly after the assembly step. Dedicated test stations at the end of the line provide final approval of the product (Figure 3).

The assembly process is managed with barcode-driven controlled work orders and a small automated feeder rack to present components to operators. Component feeding uses vibratory bowl feeders or manual loading stations to keep cycle times consistent, depending on the complexity of the part and quality constraints. Mechanical subassembly tasks (e.g. drive springs, actuator housings and reservoir seating) run on semi-automated fixtures – pneumatic presses and pick-and-place actuators perform alignment and insertion with operator loading and verification. Torque-controlled electric screwdrivers and visually-guided assembly aids ensure repeatable fastening and placement.



Figure 2: Manual workstation without carrier system.

The electronic part of the wearable device is pre-assembled offline and presented to the assembly system in trays. The integration of electronic modules into mechanical assemblies is semi-automated – either the operator loads the printed circuit board (PCB) into a fixture, where the station completes the fastening and automatic connection, or a robotic loading system performs the entire process. The final step for integrating electronics is the writing of the software onto the PCB and the following quality check. This configuration achieves ~3–5 ppm by automating the bottleneck precision tasks (e.g. preassembly, closure, flashing, test) while retaining human flexibility for changeovers, visual judgement and exception handling. It reduces manual variability, improves yield and traceability, and shortens validation time and capital investment compared with full automation.



Figure 3: Semi-automatic linear set-up.

Fully Automated Production

A fully automated assembly line for wearable injectors consists of an integrated MES engineered to minimise manual intervention and maximise product traceability. The line is located within purpose-built production zones, which incorporate enclosed automated cells that execute critical operations under controlled conditions. Facility layouts may adopt linear or cell-based configurations, depending on preferences. Material feeding is completely automated with vibratory

"A FULLY AUTOMATED ASSEMBLY LINE FOR WEARABLE INJECTORS CONSISTS OF AN INTEGRATED MES ENGINEERED TO MINIMISE MANUAL INTERVENTION AND MAXIMISE PRODUCT TRACEABILITY."

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Figure 4: Fully automated linear system.

bowls or robot-based feeding installations. Workpiece carrier systems (e.g. indexing chains or servo-driven pallets) provide synchronous transfer between feeding, subassembly, final assembly, inspection, serialisation and packaging stations. A PLC controls each production cell and manages the integrated assembly and test steps. Additionally, the process data are collected and uploaded to the MES system. The MES manages process recipes and records real-time quality and process data for regulatory compliance and process control.

The overall process flow is initiated by specialised feeding systems per component; in general, there are vibratory feeder bowls for each component. For product variants, a flexible feeder system comprising camera identification and a robotic picker is used. The most sensitive parts (i.e. PCBs and scratch-sensitive surfaces) are fed into the assembly flow by tray loaders. Due to the high investment required, this is usually the least preferred feeding solution. The actual assembly then takes place on a workpiece carrier. Depending on the assembly system set-up, the stations can be all in one frame, such as a BBS Automation linear transfer system (Figure 4), or broken up into separate cells. As the production numbers for wearable injection systems typically do not exceed 30 ppm, the latter is the more common approach.

In contrast to other high-speed assembly systems in the medical industry, cam-driven stations are not widely used in wearable injector assembly systems. There is a general preference for modular builds that allow design features to be reused, minimising engineering demands for similar applications (Figure 5). Even if a single base frame could be used for all stations, the process requirements may still require a split configuration. If some assembly steps need defined environmental controls (i.e. a Class 5 cleanroom) then a split configuration is required. This could also be triggered by the electronics integration due to electromagnetic compatibility protection.

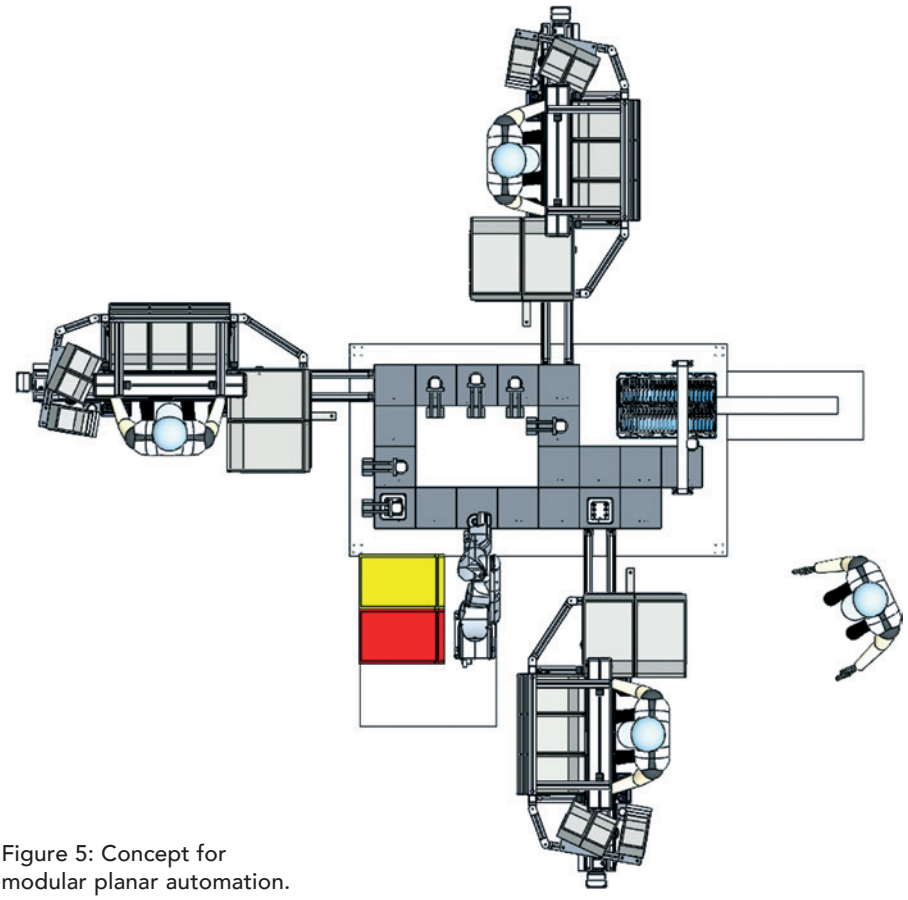


Figure 5: Concept for modular planar automation.

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Completing the set-up are the checking stations, which ensure consistent quality after each process step, limiting waste and security. Serialisation from the start ensures batch control and traceability, helping to avoid unwanted issues being identified during offline checks. By default, all process data from automated processes are transferred to the MES, linking production results to key performance indicators to support continuous improvement. From an operational perspective, the line is designed for relatively high throughput and consistent cycle times.

Automation enhances yield and process capability by mitigating human error and decreasing scrap and rework. Accordingly, workforce requirements for automated lines transition towards specialised personnel with expertise in automation maintenance, process control and quality-data analysis.

ROI JUSTIFICATION

Full automation demands substantial upfront investment and MES/PLC integration and validation. However, at high and steady volumes, the per-unit manufacturing cost falls dramatically due to lower labour, higher yield, reduced scrap and fewer quality incidents. The return on investment (ROI) is attractive when annual volumes are high enough to amortise the initial investment. Key metrics include equipment cost, expected throughput, labour savings, yield improvement, quality failure cost reduction and product lifecycle length. This results in differences in the calculations and expectations for manual assembly, semi-automated and fully automated production lines. When the ROI is a key investment criterion, low-volume expectations are a limiting factor for investment, making manual or semi-automatic assembly more attractive.

Depending on the installation region, this could still be the case for mid-volume production targets; production volumes need to reach higher numbers for fully automated installations to justify the investment. However, this requires an environment with high labour costs and strict quality requirements. If the product requires high-end technology for assembly and finish, a fully automated assembly system may be the default. The ROI then relies on the market value of the device rather than the production costs.

The ROI can also be undermined by poor product demand forecasts or a short product life, both of which can be mitigated through modular automation that can be repurposed, leasing equipment or phased investment tied to volume milestones. Robust supplier and maintenance contracts, spare parts planning and strong process validation can reduce downtime and protect the ROI.

In summary, full automation delivers the best long-term ROI for wearable injectors when demand is high and stable, product design is mature and the organisation can support the technical and regulatory complexity. For variable or early-stage programmes, a staged approach, transitioning from semi-automation to full automation as volumes justify the capital expenditure, can often optimise returns.

> "FULL AUTOMATION DELIVERS THE BEST LONG-TERM ROI FOR WEARABLE INJECTORS WHEN DEMAND IS HIGH AND STABLE, PRODUCT DESIGN IS MATURE AND THE ORGANISATION CAN SUPPORT THE TECHNICAL AND REGULATORY COMPLEXITY."

EMBEDDED QUALITY CONTROL

Quality assurance and regulatory requirements tighten as the level of automation increases, with each level shifting where risks and controls concentrate. Manual processes demand rigorous operator training, environmental monitoring and extensive sampling to mitigate human error and contamination. For the most critical assembly steps, automated tabletop test rigs can be installed. Documentation is often paper-based or semi-digital, increasing the risk of data-integrity issues.

Semi-automated set-ups reduce the variability of critical steps (e.g. assembly, screwing, adhesive dispensing) and enable targeted electronic records; however, strong operator controls and validated human-machine interfaces are still essential. Validation scope expands to include equipment qualification (i.e. installation qualification/operational qualification/performance qualification) for automated stations, software verification and calibration programmes. Specifically, software integrity and connectivity are under tight scrutiny during the qualification process. Process controls and in-process inspection points must be defined to capture automation-specific failure modes.

Fully automated systems elevate expectations for electronic data integrity, software lifecycle management and continuous process verification. Regulators expect comprehensive validation of automation, MES/PLC systems, controlled workflows and tight security for connected elements, including cybersecurity elements. Fully automated inspection can reduce end-product sampling, although validation of inspection efficacy (i.e. false positives/negatives) is still required. Traceability through serialisation and electronic batch records simplifies batch control but demands robust change control and audit trails.

Across all levels, combination product regulations apply – device and drug interfaces, extractables/leachables and biocompatibility must all still be addressed. Risk management (ISO 14971), human factors engineering and post-market surveillance remain mandatory. Automation changes the risk profile and must be reflected in the design history file, quality management system (ISO 13485) and regulatory submissions.[4]

SUMMARY

The wearable injectors market is growing due to demand for at-home therapies, chronic disease management and patient-centric care. The drive for miniaturisation, connectivity and reusable form factors is pushing boundaries to overcome current device limitations.

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At the same time, strict regulations must be adhered to and supported by full traceability. To accomplish this, assembly integrates precision mechanics, sterile fluid handling, electronics and packaging with an integral quality control. Modular subassemblies, such as drive units, reservoirs, cannulas, adhesive interfaces and electronic modules, are inspected for cleanliness and function and integrated into set-ups either manually or via automatic stations.

Assembly approaches range from manual, through semi-automatic up to fully automated systems. Manual assembly is flexible and requires minimal investment. Semi-automated lines mechanise repetitive precision tasks with PLC integration, vision aids, torque-controlled tools, barcode work orders and off-line electronic preassembly. Fully automated systems minimise manual intervention with automated feeding; synchronous transfer between feeding, subassembly, inspection, serialisation and packaging; and PLC integration for process recipes and electronic batch records, together with MES upload.

The ROI depends on volume – full automation needs high upfront investment but reduces per-unit cost at scale, while manual/semi-automated approaches suit low or variable volumes. Mitigations include modular automation, leasing, phased investment and robust supplier/maintenance contracts. The regulatory expectations for combination products apply at all levels, while automation increases the requirements for validation, electronic data integrity, software lifecycle management and cybersecurity. Overall the range of automation is a decision driven by the achievable market volume and required quality controls.



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ENSURING DEEP-COLD RELIABILITY FOR mRNA THERAPIES: ADVANCING CCI TESTING APPROACHES FOR PREFILLED SYRINGES

BD
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Dr Nesrine Rebzani and **Elsa Muller** of **BD**

discuss recent work done by the company to establish a robust methodology for testing the container closure integrity of prefillable syringes under deep-cold conditions, highlighting the challenges in establishing these methods and the value of the data acquired.

Messenger RNA (mRNA) technology has rapidly emerged as a transformative modality in modern medicine, reshaping the landscape of drug development and delivery. With their high adaptability, rapid design cycles and proven safety profiles, mRNA platforms have become a cornerstone for future prophylactic and therapeutic innovations, extending beyond covid-19 and infectious diseases to rare diseases, next-generation immunotherapies and oncology applications.[1,2]

However, unlike conventional biologics, lipid nanoparticle-based mRNA drugs are inherently unstable and often require deep-cold storage throughout the entire supply chain to preserve their integrity. Moreover, as mRNA drugs move from emergency use to broader clinical adoption across multiple therapeutic areas, the focus is shifting from speed to reliability, manufacturability, cost efficiency and lifecycle sustainability.

This evolution brings the need for more advanced primary packaging solutions. Indeed, the industry is progressively moving from multi-dose vials to single-dose prefilled syringes (PFSs), a format that simplifies preparation, reduces waste and improves dosing accuracy.[3–5]

Moving mRNA formulations into PFS systems introduces new technical challenges. Unlike vials, syringes are complex assemblies combining multiple components and parameters: barrel, lubricant, and closure systems (plunger stoppers & tip cap), each with distinct thermal and mechanical properties. Under frozen

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conditions, differences in thermal expansion coefficients can affect container closure integrity (CCI).

Different analytical techniques exist today to assess CCI performance. Each method comes with intrinsic limitations when applied to deep-cold conditions, where material behaviours, phase transitions and frozen interfaces challenge conventional testing paradigms. There is a growing need to better understand which techniques can reliably characterise syringe performance under frozen storage conditions and where current industry practices may currently fall short.

Recognising these challenges, BD has conducted an in-depth evaluation of commonly used CCI techniques in the context of deep-cold storage. Through systematic investigation of method-specific limitations and stress conditions, BD has developed an in-house testing framework that integrates complementary analytical techniques and tailored testing parameters to better simulate actual frozen conditions and reduce methodological bias.

The objective of this article is to review the capabilities and limitations of existing CCI testing approaches in deep-cold conditions and to present the rationale and outcomes of BD's dedicated methodology. The insights generated through this work not only contribute to a more accurate understanding of syringe performance under frozen storage but also provide valuable perspective on the suitability of BD's PFS portfolio for mRNA-based applications requiring deep-cold conditions. By addressing these challenges, BD aims to contribute to the safe, reliable and scalable deployment of the next-generation of mRNA vaccines – reinforcing its role as a trusted partner in enabling innovation across the vaccine ecosystem.

"BD HAS DEVELOPED AN IN-HOUSE TESTING FRAMEWORK THAT INTEGRATES COMPLEMENTARY ANALYTICAL TECHNIQUES AND TAILORED TESTING PARAMETERS TO BETTER SIMULATE ACTUAL FROZEN CONDITIONS AND REDUCE METHODOLOGICAL BIAS."

LIMITS OF CONVENTIONAL CCI METHODS FOR DEEP-COLD STORAGE APPLICATIONS

Based on preliminary internal studies and available literature,[6,7] CCI is a critical consideration as storage temperatures decrease, with direct implications for sterility and product stability under deep-cold conditions. Historically, dye ingress tests, such as the methylene blue method, have been widely used for CCI verification.[8] These tests are considered probabilistic methods, relying on visual detection of dye penetration through potential leak paths under defined test conditions. While simple and widely implemented, probabilistic approaches inherently provide a binary pass/fail outcome, without quantifying leak size or enabling predictive assessment of package performance.

Beyond these intrinsic limitations, dye ingress testing is particularly challenged in deep-cold storage scenarios. While effective at room temperature, it may fail to capture transient integrity losses occurring under frozen conditions (Figure 1). When samples are cooled and subsequently returned to ambient conditions for testing, elastomeric components may reseal due to material relaxation, masking failures and generating false negatives.[6,9]

The physics behind this phenomenon is straightforward: elastomeric plunger stoppers contract more than glass barrels at low temperatures, potentially creating temporary leak paths. Upon warming, the elastomer expands, restoring the seal. This dynamic behaviour underscores the need for methodologies capable of evaluating integrity during or immediately after deep-cold exposure. It also highlights the broader advantage of deterministic, quantitative CCI methods, which offer improved sensitivity and more reliable performance characterisation under challenging storage conditions.

Among these deterministic methods, headspace gas analysis has emerged as a particularly relevant solution for evaluating CCI under deep-cold conditions. The principle of the test is that the system samples (syringe, tip cap and stopper) are conditioned in a freezer preset to the target qualification temperature. The freezer is saturated with CO_2 by placing trays of dry ice (i.e. solid CO_2) inside for at least 24 hours before and throughout sample storage. If a transient leak path forms at deep-cold temperature, CO_2 present in the freezer can enter the syringe. Upon removal from the freezer, elastomeric components re-seal during thawing, thereby trapping any ingressed CO_2 within the headspace.

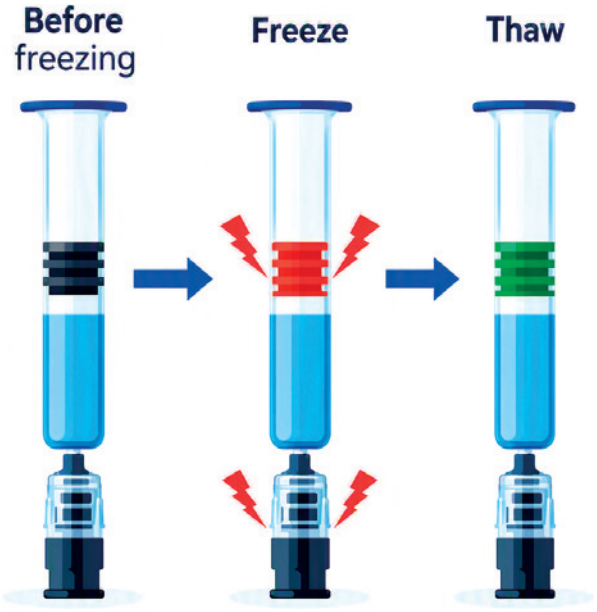


Figure 1: Schema of the transient integrity losses that can occur under frozen conditions.

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After conditioning, the CO_2 partial pressure in each syringe headspace is quantified using a Lighthouse Instruments (Charlottesville, VA, US) frequency modulation spectroscopy (FMS) CO_2 headspace analyser. Each syringe is positioned in the instrument to perform a non-destructive, quantitative measurement of headspace CO_2 partial pressure. The number of test samples is defined upstream based on the desired statistical confidence and reliability; positive and negative controls are included in every run to confirm method sensitivity and discrimination.

Helium leak testing can also be used and remains a valuable tool for exploring the limits of system performance and identifying potential failure points at specific interfaces, such as the tip cap/tip interface or plunger stopper/barrel interface. Together, these complementary methods provide a comprehensive understanding of CCI under extreme conditions.

DEVELOPING A ROBUST, IN-HOUSE, DETERMINISTIC HEADSPACE METHODOLOGY

While deterministic methods such as headspace gas analysis provide clear advantages over probabilistic approaches, their reliability in deep-cold applications depends heavily on methodological rigour. BD's early evaluations demonstrated that conventional headspace testing protocols could be significantly influenced by uncontrolled variables, including the time between freezer removal and measurement, CO_2 saturation consistency, equilibration time and instrument calibration stability. In deep-cold studies, these parameters can materially impact results, potentially introducing variability that obscures true system performance.

To address these challenges, BD developed its own deep-cold headspace CCI method, in line with BD's established design verification rigour. This structured, stepwise approach aimed to identify, understand and control the parameters that could impact measurement accuracy, sensitivity and repeatability.

The first step was to select the temperature for this methodology. The glass transition temperature (Tg) of elastomeric components is approximately –65°C, where material properties change significantly.[9] BD selected –50°C to approach this critical zone while accommodating freezer variability (±5°C) and aligning with industry requirements for mRNA vaccine storage. This choice reflects a balance between scientific rigour and practical feasibility. The second step in developing the methodology was to characterise each key factor and incorporate them into the final validated protocol, ensuring a scientifically robust and reliable method.

> "WHILE DETERMINISTIC METHODS SUCH AS HEADSPACE GAS ANALYSIS PROVIDE CLEAR ADVANTAGES OVER PROBABILISTIC APPROACHES, THEIR RELIABILITY IN DEEP-COLD APPLICATIONS DEPENDS HEAVILY ON METHODOLOGICAL RIGOUR."

Freezer Temperature and Thermal Homogeneity

One of the first critical areas investigated was the thermal environment inside the freezer. Real-world freezers do not maintain a perfectly stable temperature; instead, they oscillate and exhibit spatial variations. To guarantee consistent stress across all samples, the entire freezer volume was mapped to characterise its temperature gradients. Based on this mapping, the setpoint was adjusted so that the average measured temperature inside the most homogeneous region remained centred around –53°C, ensuring that the temperature consistently remained below –50°C throughout the entire test. Placing samples only within this stable zone ensured that each syringe experienced the same thermal conditions throughout storage, including exposure to the natural low-end fluctuations inherent to deep-cold equipment – an additional margin that reinforces confidence in the system's suitability for temperatures at or below the intended range.

CO_2 Gas Availability and Exposure Duration

BD also evaluated the ability of the freezer chamber to maintain a sufficiently high CO_2 gas concentration. Since the method relies on CO_2 ingress through leaks that occur during freezing, the presence of CO_2

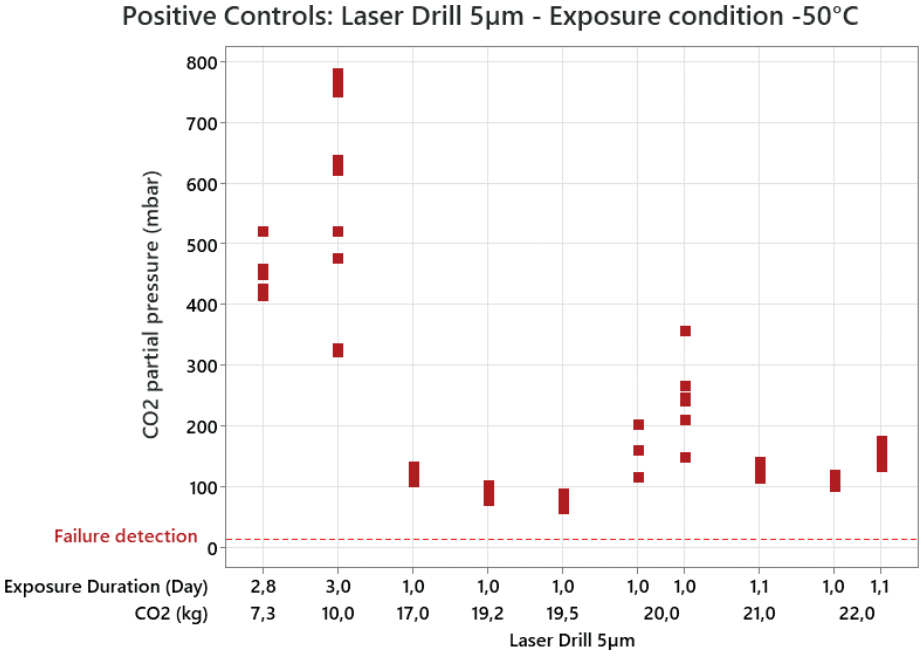


Figure 2: Partial pressure measured in the samples with different CO_2 gas quantities and exposure times.

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inside the freezer is essential. Dry ice trays were therefore arranged strategically – not near the samples, where they could produce local overcooling, but in the areas where temperature fluctuation was highest. This placement allowed the entire freezer to saturate with CO_2 gas in a controlled manner.

The team also examined how the amount of dry ice and the actual freezer temperature affected sublimation rates and thus exposure time. As colder temperatures slow sublimation, lower freezer temperatures require longer CO_2 exposure to achieve consistent saturation. This analysis ensured that every sample received enough exposure to avoid false negative results caused by insufficient CO_2 availability (Figure 2).

To further confirm that the freezer atmosphere remained properly saturated with CO_2 throughout conditioning, BD also included dedicated environmental control samples inside the chamber. These controls consisted of syringes with deliberately drilled holes, creating a temporary leak path that closes again during thawing. Because these samples are guaranteed to admit CO_2 whenever it is present in the freezer, the measurement of their headspace CO_2 concentration at the end of the test provides a direct verification of the actual vapour exposure conditions. Analysing these environmental controls in parallel with the test samples ensures that the freezer contained an adequate and consistent amount of CO_2 during the entire conditioning phase, therefore confirming that all syringes under evaluation were exposed to the required CO_2 levels necessary for reliable CCI assessment (Figure 3).

Based on experimental observations, BD established 400 mbar as the reference pressure for environmental controls. Here, CO_2 ingress consistently produced a clear, stable and repeatable headspace signal after thawing, making it a reliable benchmark to confirm that the freezer atmosphere was adequately saturated during testing.

Acceptance Criteria and Control Strategy

For intact syringes, the baseline corresponds to the measurement resolution of the Lighthouse FMS CO_2 analyser, where the smallest standard aligns with 0±13 mbar. BD therefore defined the CCI acceptance limit as any measurement below 13 mbar, establishing a clear criterion for passing

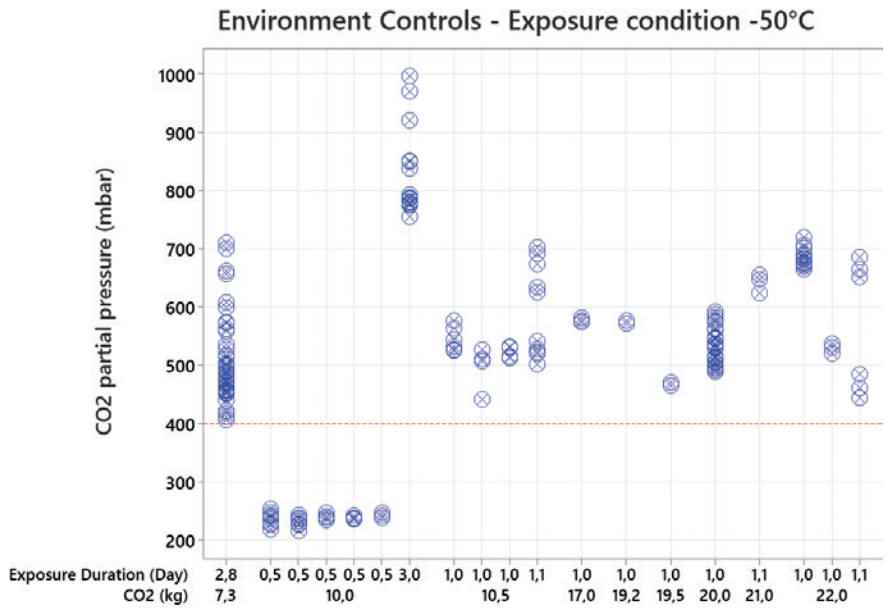


Figure 3: Partial pressure measured in the environmental control samples with different CO_2 gas quantities and exposure times.

samples. This creates a stringent yet realistic definition of "no gas ingress" anchored in the technical capabilities of the analytical device.

To ensure that the method could reliably detect any loss of CCI, BD used dedicated positive control samples engineered with drilled leak paths of different diameters. Unlike environmental controls, these leak paths remain open throughout freezing and thawing and therefore do not reseal at any point during the test. Because they continuously allow CO_2 to enter the syringe during conditioning, their final headspace CO_2 pressure must be well above the analytical detection threshold of 13 mbar. Confirming that positive controls consistently fall within this expected pressure range provides strong assurance that the test conditions were sufficiently

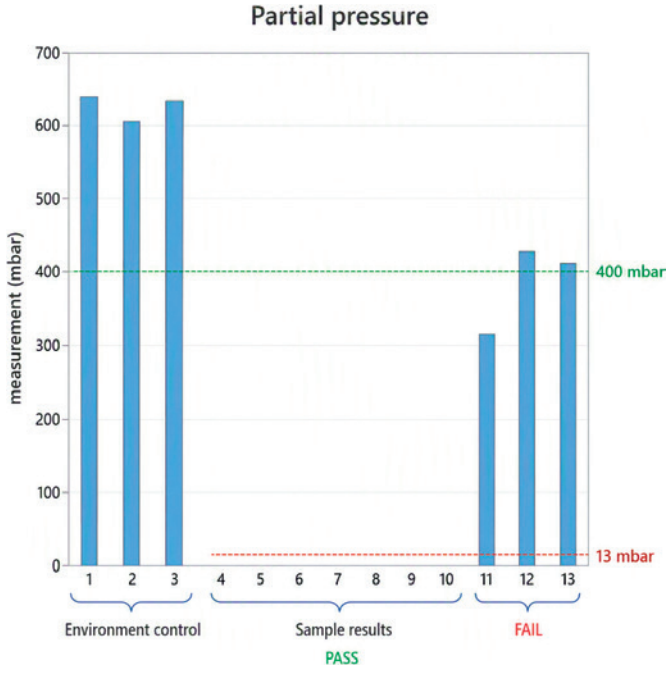


Figure 4: Comparison between tested samples with no CCI fail and the positive controls samples.

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stringent and that any sample exhibiting a leak would indeed accumulate detectable CO_2 (Figure 4). In other words, these positive controls play a critical role in preventing false negatives by demonstrating that the method would have identified CO_2 ingress if it had occurred in the test samples.

Empty versus Filled Syringe – Rationale for Method Validation

During method development, both filled and empty syringes were assessed to determine which configuration would provide the most stable and repeatable measurement. In filled syringes, the presence of a water meniscus significantly reduces the headspace volume and alters its geometry, making the CO_2 reading more sensitive to small variations in positioning, frost formation or optical disturbances.

Frost near the cone end was found to exacerbate these issues, leading to inconsistent or noisy measurements. In addition, once the water freezes, the ice at the tip physically seals the tip cap interface, preventing any assessment of whether this portion of the system maintains closure integrity under frozen conditions. The water-to-ice transition also introduces an additional complication – as water solidifies, its volume increases by roughly 10%, generating internal expansion forces that can push the plunger stopper forwards. This displacement further reduces the available headspace and adds variability to the measurement, making filled syringes inherently less reliable for developing a robust and deterministic CCI method.

For these reasons, BD validated the method using empty syringes. Doing so maximises the headspace volume and therefore stabilises the measurement, while also ensuring that both critical interfaces – the plunger stopper/barrel and the tip cap/barrel – remain fully assessable. This configuration provides a conservative, repeatable and comprehensive evaluation of syringe system performance in deep-cold environments.

Time from Freezer to Measurement (Thawing Window)

Another parameter was the time between removal from the freezer and measurement. During thawing, BD also monitored positive controls equipped with permanent leak paths. Because these openings remain active once the samples are removed from the freezer, any CO_2 that entered during conditioning can progressively escape while the syringe equilibrates to ambient temperature. This makes these permanently open controls highly sensitive indicators of CO_2 loss during the post-freezer handling period.

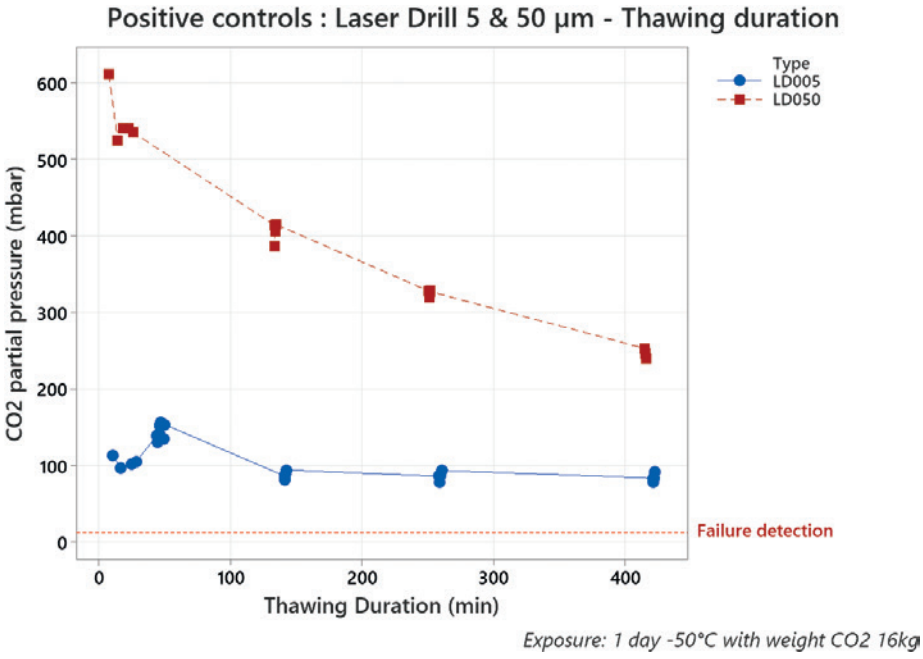


Figure 5: Partial pressure measured in the positive controls samples for different thawing times.

When evaluated at the same time as the test samples, they provide a direct check on whether the elapsed time between freezer removal and headspace measurement was adequately controlled: if a positive control shows a substantial loss of CO_2 by the time it is measured, it suggests that leaking test samples could similarly have lost part of their CO_2 signal,

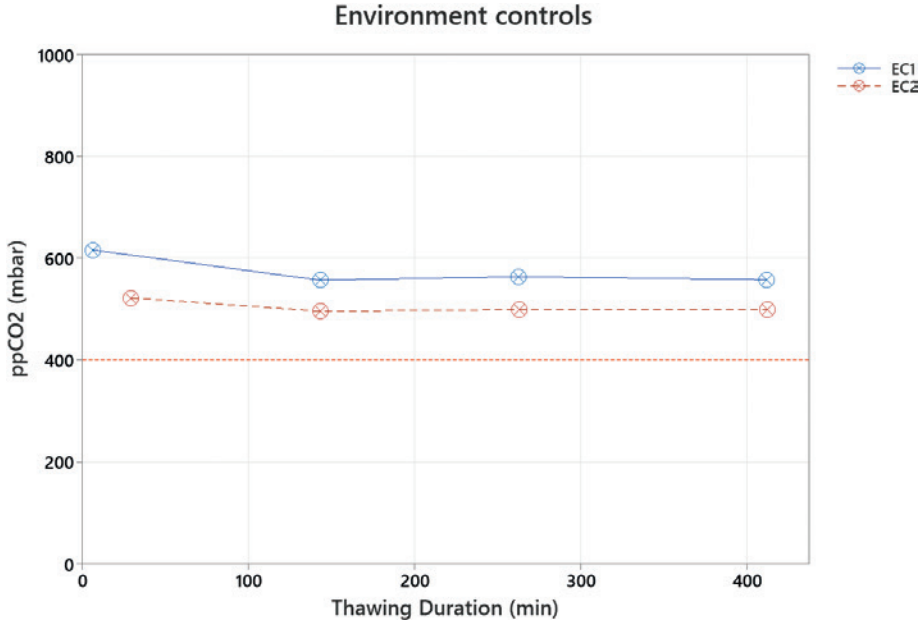


Figure 6: Partial pressure measured in the environmental control for different thawing times.

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increasing the risk of false-negative results. By tracking the behaviour of these controls, BD can therefore verify that the thawing window is properly respected and that the method maintains its intended sensitivity throughout the entire handling process (Figures 5 & 6). To maintain both repeatability and discriminatory power, the protocol caps the allowable elapsed time to four hours. This ensures that all samples, both intact and defective, are evaluated under comparable and scientifically justified conditions.

While headspace analysis is broadly used within the industry, the quality of the data generated depends on methodological rigour. BD's strengthened approach not only supports regulatory compliance but also enables a deeper and more reliable understanding of syringe performance under extreme-cold conditions, providing greater confidence in data interpretation for pharmaceutical partners developing sensitive mRNA drugs.

IN-HOUSE DEEP-COLD CCI HEADSPACE METHODOLOGY APPLIED TO BD VACCINE PFS PORTFOLIO

The study was conducted on the following BD syringe systems: BD Effivax™ Glass Prefillable Syringe and BD Hypak™ for Vaccine Glass Prefillable Syringe, with PRTC FM30 and 7025/65 formulations assembled with FM457 plunger stoppers. Samples were stored for one week at –50°C prior to the first CCI assessment and subsequently subjected to five freeze/thaw cycles (–50°C to ambient), with

Storage condition	Result
T0	Pass
3 months at -50°C + 5 cycles at -50°C	Pass
6 months at -50°C + 5 cycles at -50°C	Pass
12 months at -50°C + 5 cycles at -50°C	Pass

Table 1: CCI performance of BD vaccine prefillable syringes under deep-cold conditions.

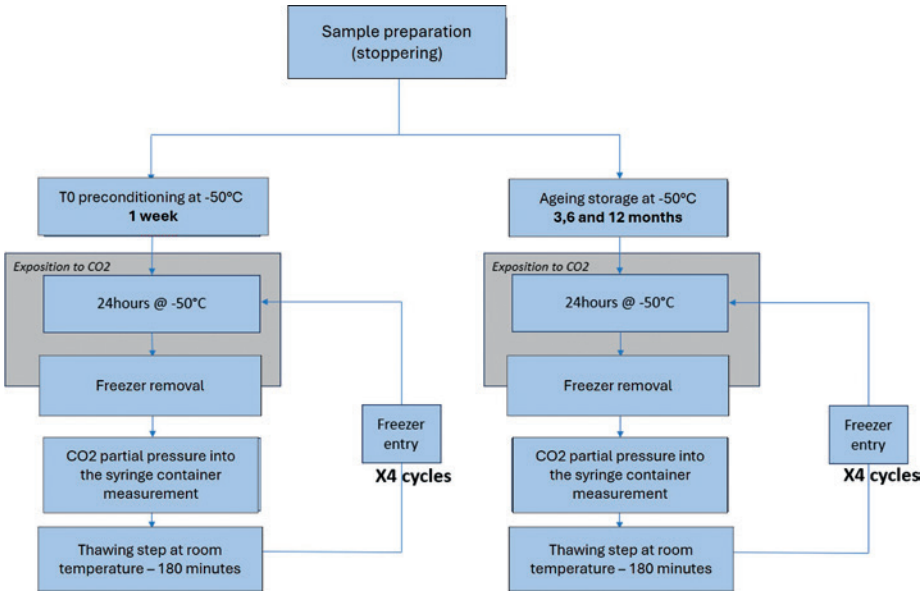


Figure 7: Sample conditioning for CCI assessment.

headspace CCI measured after each cycle. In addition, a subset of samples underwent long-term ageing at –50°C for up to 12 months and then completed five additional freeze/thaw cycles prior to CCIT (Figure 7).

Across all evaluated configurations and conditions, no tested sample exhibited CO_2 ingress. All measured headspace CO_2 partial pressures for test articles remained below the 13 mbar specification, the positive controls were above 13 mbar and the environment controls were above 400 mbar as defined in the test method, confirming method sensitivity and discrimination.

The absence of failures persisted after five freeze/thaw cycles and after long-term ageing at –50°C for up to 12 months, indicating that deep-cold storage did not adversely impact CCI for the systems tested (Table 1).

In addition to internal validation, BD reinforced the credibility of its approach by comparing its headspace analysis results with other complementary techniques. These independent tests consistently converged towards the same conclusions and values, confirming the relevance of the headspace analysis method and strengthening confidence in its reliability. This comparison with other complementary techniques, combined with BD's systematic approach, underscores the company's strong expertise in deep-cold CCIT and its commitment to scientific rigour in primary packaging solutions.

FUNCTIONAL TESTS PERFORMED ON BD VACCINE PORTFOLIO UNDER DEEP-COLD CONDITIONS

Functional tests were also performed on the same sample configurations using design verification test methods to confirm system functionality. The methods used are those described in ISO 11040-4:2024, which specifies requirements for glass PFSs intended for parenteral use, including dimensional, mechanical and performance criteria (Table 2). The same was done with ISO 80369 standards, including -7 and -20, covering the standardised connectivity of Luer locks with small bore connectors (Table 3). For these evaluations, syringes were filled with ultrapure water, sealed with BD SCF™ plunger stoppers (FM457 formulation) and subjected to up to 10 freeze/thaw cycles at -80°C, as well as long-term ageing for up to 12 months at -80 °C.

Although the primary objective of the study was to characterise the syringe system performances in deep-cold storage conditions at -50°C, the functional evaluations were intentionally conducted at –80°C. This choice reflects a science-driven rationale – among all syringe system attributes, CCI is known to be the

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ISO 11040-4	Storage condition	Result
Tip cap pressure leak resistance	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
RC Unscrewing	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
RC Pull out Force	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
LLA Pull out Force	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
LLA Torque	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass

Table 2: Functional performance of BD vaccine prefillable syringes under deep-cold conditions according to ISO 11040-4.

ISO 80369-7	Storage condition	Result
Leakage by pressure decay	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
Sub-atmospheric pressure air leakage	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
Stress cracking resistance	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
Resistance to separation from axial load	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
Resistance to separation from unscrewing	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass
Resistance to overriding	10 cycles (T0 months)	Pass
	Ageing 12 months	Pass

Table 3: Luer connection performance of BD vaccine prefillable syringes under deep-cold conditions according to ISO 80369-7.

"SELECTING THE RIGHT TECHNICAL PARTNER, WITH AN APPROPRIATE CCI METHODOLOGY IS ESSENTIAL TO SUPPORT RELIABLE RISK ASSESSMENT UNDER EXTREME CONDITIONS."

most sensitive to extreme cold, whereas mechanical and functional performances typically remain robust well below the temperatures at which leakage risks begin to emerge. By performing functional tests directly at –80 °C, BD applied a conservative, worst-case approach that intentionally goes beyond the expected operating range.

Demonstrating that all mechanical and performance criteria remained fully compliant at such extreme temperatures confirms that these characteristics are not the limiting factor of the system. Consequently, it highlights that CCI is the first attribute to be challenged under deep-cold conditions, thereby validating the relevance of using CCI outcomes to define the true operational boundary of syringe systems. Across all tested conditions, including multiple freeze/thaw cycles and extended ageing, the tested syringe systems exhibited no evidence of detrimental impact on functional performance when compared with reference populations after storage at –50°C.

CONCLUSION

CCIT is no longer a peripheral requirement in drug development, it is a critical success factor, particularly for temperature-sensitive formulations and mRNA applications that may require frozen or deep-cold storage. Selecting the right technical partner, with an appropriate CCI methodology is essential to support reliable risk assessment under extreme conditions.

Deep-cold storage must be considered as a system-level challenge. Syringe performance does not rely on a single component but on the interaction between the barrel, elastomeric closures and the overall assembly under thermal stress. As a fully integrated provider of both glass barrels and elastomeric components, BD is strongly positioned to evaluate and understand the behaviour of these systems holistically.

Under deep-cold conditions, CCIT becomes particularly challenging, as temporary leak paths may occur during frozen storage and disappear once samples return to ambient temperature. While headspace analysis is a highly relevant approach to assess CCI under these conditions, data reliability still depends on the rigour of the methodology.

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BD's approach supports the generation of more relevant deep-cold CCI data by identifying and carefully controlling critical parameters, such as freezer temperature homogeneity, CO_2 availability, exposure duration and thawing window. The reliability of this methodology is further reinforced by the careful selection and challenge of positive and environmental controls, as well as clearly defined acceptance criteria, ensuring that the methodology can discriminate true CCI performance from potential bias.

This methodology provides a scientifically rigorous framework to evaluate syringe system behaviour under frozen storage conditions and strengthens confidence in data interpretation for pharmaceutical partners developing mRNA applications. The data generated in this study demonstrate the consistent performance of BD's vaccine syringe platforms under extreme conditions, supporting pharmaceutical companies in the selection of primary packaging solutions and in de-risking their development processes.

These results are intended to support customer decision-making and provide scientific insight into system behaviour under deep-cold storage. Importantly, these findings do not replace formal design verification testing required for regulatory submission. Full verification studies must be conducted in alignment with specific drug formulations, process parameters and regulatory expectations. By combining integrated component expertise, robust methodology and system-level understanding, BD positions itself as a trusted partner for pharmaceutical companies developing next-generation mRNA drugs requiring deep-cold storage.

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Team Consulting is a fee-for-service consultancy that works with pharma and medtech clients to design and develop medical devices, in particular drug delivery devices. In the field of drug delivery, Team Consulting's focus is on administration via the respiratory and parenteral routes.

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Unither Pharmaceuticals is a pharmaceutical subcontractor specialising in the development and manufacturing of single-dose and multidose liquid formulations (including eye drops, saline solutions, asthma medications in BFS single doses and oral liquid stick-packs) for originator pharmaceutical companies and generic manufacturers. Recent innovations have led the CDMO to launch Euroject – an innovative BFS-based device for single-dose injection of therapeutics.

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West Pharmaceutical Services is a provider of innovative, high-quality injectable solutions and services. As a trusted partner to established and emerging drug developers, West helps ensure the safe, effective containment and delivery of life-saving and life-enhancing medicines. With over 10,000 team members across 50 sites worldwide, West helps support its customers by delivering approximately 43 billion components and devices each year.

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ZwickRoell provides testing solutions for medical devices, drug delivery systems and pharmaceutical packaging. Its portfolio supports quality, safety and regulatory compliance from development to quality control and lot release. In-house developed testing machines and software ensure accurate, reproducible results for GMP environments. With 1,900 employees in over 50 countries, ZwickRoell supports manufacturers worldwide.

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Instron manufactures and services a wide range of mechanical testing equipment used in the design and production of drug delivery devices. A strategic partner to global companies of all sizes, Instron helps its partners investigate new technologies and ensure product quality while maintaining the highest levels of data integrity and security.

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IGS GeboJagema is a high-precision mould maker that designs, manufactures, validates and maintains moulds for products where extreme precision is vital, from glasses and contact lenses to asthma inhalers, insulin pens and blood diagnostic devices. IGS GeboJagema specialises in collaborating with medical original equipment manufacturers early in the product lifecycle, allowing its exceptional engineering team to develop innovative moulding solutions.

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KERN LIEBERS is a medium-sized family business headquartered in southwestern Germany. Its Smart Springs and Smart Parts are intelligent functional components developed to meet the highest technical requirements and deliver maximum functionality. Each spring and each part not only fulfills a specific task – it also assumes responsibility for the functionality and reliability of the entire system at over 40 locations worldwide.

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Kindeva Drug Delivery is a global CDMO focused on drug-device combination products. The company develops and manufactures products across a broad range of drug-delivery formats, including pulmonary and nasal, injectable and transdermal. Its service offerings span early-stage feasibility through to commercial-scale drug product fill-finish, container closure system manufacturing and drug-device product assembly.

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Lifecore is a CDMO specialising in the development, fill/finish and commercialisation of sterile injectables, biologics, medical devices and combination products. With an over 40-year regulatory track record and more than 20 commercial products, Lifecore offers end-to-end services including formulation process development, aseptic fill/finish, analytical, packaging and stability studies. Capabilities include expertise with highly viscous products.

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Nemera is a drug delivery device solutions and combination product services provider that puts patients first to enable the design and manufacture of devices that maximise treatment efficacy. Nemera is committed to the highest quality standards, from early device strategy to state-of-the-art manufacturing. Nemera works closely with customers to ensure the success of their combination products.

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Established in 1954, **NIPRO PharmaPackaging** is a global manufacturer of comprehensive pharma packaging solutions for the pharmaceutical industry. From glass tubing to finished products, the company commits its expertise and services to carefully master drug product requirements.

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Quvara Medical is a UK-based CMO specialising in precision medical devices for injectable drug delivery. With more than 30 years of heritage, Quvara combines validated cleanroom capacity, regulatory expertise and scalable manufacturing to support pharma and biotech partners from development through to commercial supply, delivering quality, compliance and speed to market.

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RPK Medical, part of RPK Group, specialises in creating custom solutions in springs, stamping bending and assemblies, operating six factories across Europe, North America and Asia, and employing more than 800 people. The company ensures quality through tailored cleaning and packaging in cleanrooms worldwide.

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SCHOTT Pharma is a provider of drug containment and delivery solutions for injectables, ranging from prefillable syringes, to cartridges, vials, and ampoules. It manufactures syriQ BioPure® glass prefillable syringes for biologics, and SCHOTT TOPPAC prefillable syringes, made of COP.

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Ensera is a global partner for injectable drug delivery and combination product programmes. With expertise spanning device development, manufacturing, final assembly, packaging and commercialisation, it helps pharmaceutical companies transform complex product concepts into market-ready therapies through a flexible, integrated development and supply model.

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SHL Medical designs, develops and manufactures self-injection solutions, such as autoinjectors, pen injectors and specialty delivery systems for large-volume and high-viscosity formulations. By partnering with leading pharma and biotech companies, SHL Medical will continue to develop and supply products and services to support, engage and oversee patients whose quality of life relies on innovative self-treatment therapies.

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Aptar Pharma offers proven drug delivery solutions and services that support pharmaceutical companies worldwide to develop safe, efficient and compliant medicines. Aptar Pharma's drug delivery systems, components and active material solutions serve the widest range of delivery routes, Aptar's digital healthcare solutions help improve patient adherence and Aptar Pharma Services helps accelerate and derisk development.

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DCA is a product design consultancy with a wealth of experience developing leading drug delivery devices for global markets, including all types of injection, infusion, inhalation, intranasal, oral and topical devices. DCA provides comprehensive, expert support for device design and development, including strategy, usability, connectivity, engineering, electronics, medical device software and industrialisation.

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