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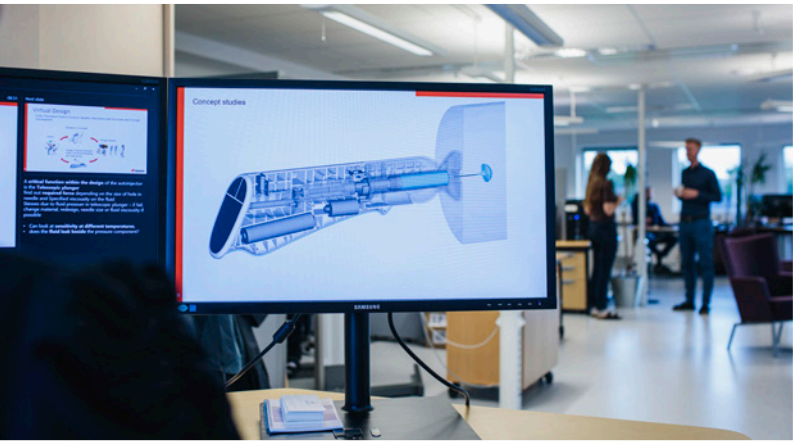

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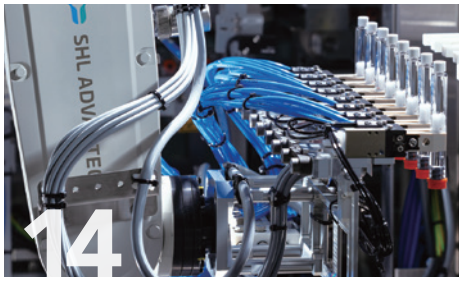
Contents



INDUSTRIALISING DRUG DELIVERY

ONdrugDelivery Issue N° 175, July 3rd, 2025

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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Adaptability and Reliability: Manufacturing in a Changing World

In this issue of ONdrugDelivery, we cover the subject of industrialisation in the modern drug delivery landscape. With increasing uncertainty affecting global supply chains, ensuring that the pharmaceutical industry has access to robust, flexible and sustainable manufacturing capabilities from clinical to commercial scale is a critical challenge facing suppliers and CDMOs around the world. The issue includes contributors from across the sector, including device manufacturers, CDMOs, specialist consultancies and equipment providers.

The issue opens with an article from **Ypsomed**, our Outstanding Sponsor (Page 8), focusing on the manufacturing of self-injection devices. The article dives into how the modern trend on platform-based device design can be part of a broader strategy to ensure smooth scale-up and reliable supply.

Digging deeper into the key theme of the issue, we feature a trio of interviews from **SHL Advantec**, our Key Sponsor (Page 14), on the sub-group's establishment and the services it can provide to pharma partners; **Phillips Medisize** (Page 36) on the company's acquisition of Vectura; and **Nolato** (Page 52) on the value of virtual tools and decentralisation when scaling up from early prototyping to commercial manufacturing.

Adding to the discussion, this issue features contributions from multiple CDMOs operating in the drug delivery sector. Taking a broad view, **Sanner Group** (Page 20) discusses the role that CDMOs can play in global industrialisation strategies, while others provide more specific insights – **Bespak** (Page 26), an inhalation specialist, considers the ongoing transition to more sustainable propellants in metered dose inhalers and **Pfizer CentreOne** (Page 44) focuses on sterility, a critical aspect of manufacturing injectables.

A major topic in current conversations around drug delivery is regulation, and this issue of ONdrugDelivery is no exception, including two articles that tackle this key subject. First, **West Pharmaceutical Services** (Page 32) reviews the standards and regulatory landscape surrounding storage and shelf life for combination products. Following on from this, **IMed Consultancy** and **JAGGAER** (Page 48) unpack the changing regulatory expectations and requirements surrounding post-market surveillance.

Rounding out the issue, **Sapphire Inspection Systems** (Page 40) comments on the value that modern automated X-ray inspection systems can offer to quality control in pharmaceutical manufacturing, including the potential for artificial intelligence and machine learning technologies to enhance their reliability and potential.

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SELF-INJECTION DEVICE MANUFACTURING IN A DYNAMIC WORLD

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Philipp Richard of **Ypsomed** scrutinises the efficient production of self-injection devices in the pharma industry and describes Ypsomed's own platforms for developing these devices, highlighting the need to be adaptable and resilient to the rapidly evolving world of drug development. He provides valuable insights into the ways in which the flexible manufacture of self-injection devices might be achieved.

THE EVOLUTION OF SELF-INJECTION DEVICES

Fifty years ago, the advent of biotechnology heralded a new era of novel drugs. With complex molecules unsuitable for oral administration, injection-based systems were required to deliver the drug either directly into the bloodstream or under the skin. The latter route, subcutaneous injection, gave rise to a field of self-injection devices that enable patients to safely and conveniently take the drug themselves.

To begin with, the majority of these devices delivered insulin and were, with designs inspired by ballpoint pens, devices that used prefilled cartridges containing the drug. With the advent of the prefilled syringe (PFS), self-injection entered the scene for the delivery of single-fixed doses, driven by the need to administer non-preserved formulations of monoclonal antibodies.

At first, reusable systems prevailed and the overall need for self-injection devices was comparably low due to their long service life and limited overall demand. Back then, these devices were considered functional secondary packaging, manufactured mostly by big pharma for its own needs. Outside of this, only a limited number of specialised suppliers, such as Ypsomed, offered design and manufacturing capabilities. At this stage, regulations were more lenient, and the focus was on simple solutions that could elevate the established standard of care (i.e. vial and syringes) in terms of user-friendliness and accuracy.

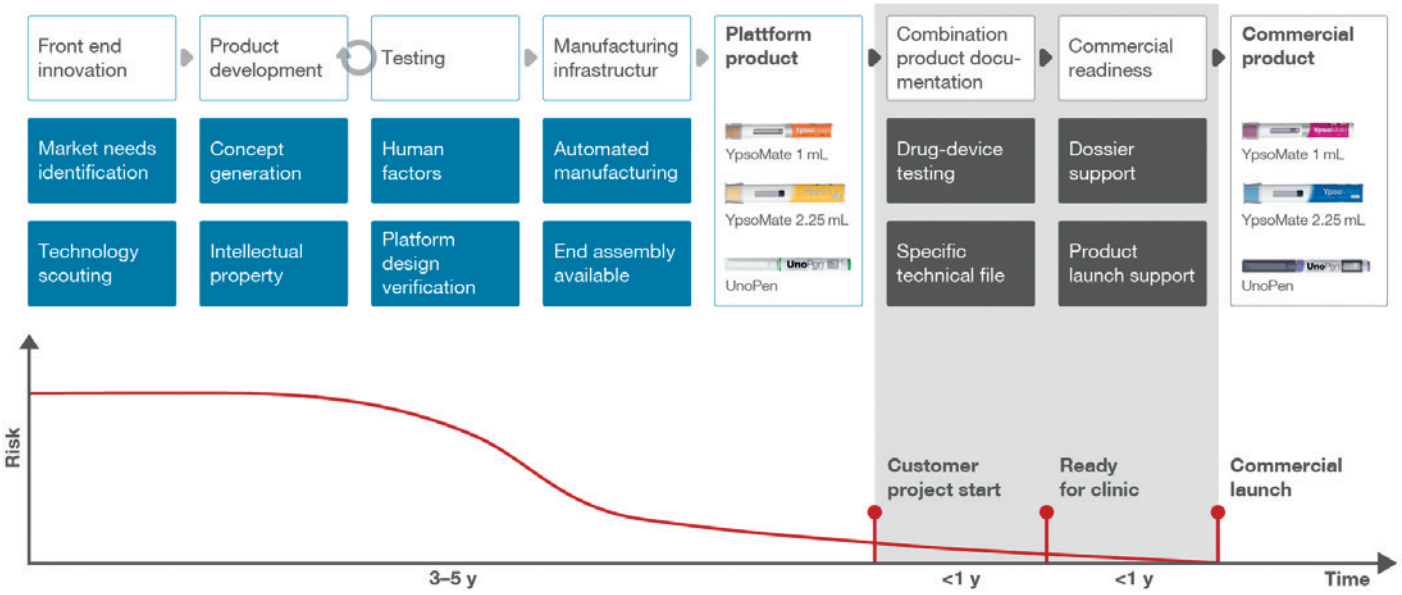

Figure 1: Ypsomed's platform strategy accelerates time-to-market, leveraging modular autoinjector components that are adaptable for diverse drugs and patient needs.

FROM REUSABLE SYSTEMS TO PREFILLED DEVICES

As the market evolved in the early 2000s, usability became an important design consideration. Convenient, prefilled pen injectors were rolled out to serve the needs of an exploding population of insulin-dependent Type 2 diabetics with second-generation synthetic insulins. In the same period, the first autoinjectors for the administration of TNF-α inhibiting monoclonal antibodies were successfully launched and sold in increasing numbers.

This shift from reusable systems, regulated as medical devices, to ever-growing numbers of prefilled products, regulated as combination or medicinal products, also required new regulatory capabilities in the pharma industry. The strong growth in this period highlighted the limits and risks in the existing setup of supply chains for devices that were supporting multi-billion drug franchises. Big pharma started to either build up massive manufacturing capacity in-house or started collaborating with a growing network of contract manufacturers that would operate multiple manufacturing lines for the same product.

"THE STRONG GROWTH IN THIS PERIOD HIGHLIGHTED THE LIMITS AND RISKS IN THE EXISTING SETUP OF SUPPLY CHAINS FOR DEVICES THAT WERE SUPPORTING MULTI-BILLION DRUG FRANCHISES."

At the same time, it became apparent that the traditional approach towards development, industrialisation and manufacturing of self-injection devices – that is, the deployment of a bespoke device for each drug – was not fast enough to ensure desired time to market, was too expensive, and also too risky given the rate of attrition in drug development pipelines.

THE SHIFT TO PLATFORM-BASED DEVELOPMENT

Based on these circumstances, Ypsomed moved rapidly to develop its platform approach, which it introduced in 2010. The platform approach offers pre-developed devices that are ready for production using a flexible and shared manufacturing setup (Figure 1). With such platforms, the main drawbacks of the traditional approach could be mitigated, and time to clinic, as well as time to market, for any drug in a self-injection device could be considerably lowered at a fraction of the cost of bespoke development. Thus, the barriers to accessing state-of-the-art self-injection devices were lowered, which also opened new possibilities for the rising biosimilars industry.

Nowadays, platforms are an established business and manufacturing model that have given rise to a networked industry of consultancies, design companies, device companies, manufacturing equipment suppliers, primary container companies and contract manufacturing organisations.

Yet, challenges remain, such as manufacturing flexibility, speed of scale-up and continuity of supply, calling for specific solutions at various levels. This is because at the end of the day, as has been the case ever since the approval of the first recombinant insulin by the US FDA in 1982, patients need their pharmacy to have the drugs they need in stock at all times.

ADDRESSING FLEXIBILITY AND SCALE-UP CHALLENGES

In consumer goods and cars, the "batch size of one" or fully customised product, has become the holy grail and has shaped expectations. However, manufacturing pharmaceuticals is historically a volume business, driven by batch production and large upfront investments in highly specialised facilities dedicated to a single

asset. The same applies to the manufacture of medical devices, which ask for tooling and assembly equipment with long lead times.

Both factors work against flexible manufacturing (i.e. building different products or product variants in variable lot sizes on the same production line). While adjusting lot sizes is straightforward in principle, it might raise questions about economic viability if the ratio of lot sizes to the output of a line is low. So, the volume flexibility needed for clinical studies (e.g. low volumes of several product variants for different dose strengths) must be supported by equipment with suitably high flexibility and limited output.

More complex, however, is the sort of flexibility that enables the manufacture of several product variants on the same highly automated production line. This flexibility must be built into the design of the delivery device by considering a parameter space that covers all potential drugs and by designing it for a broad user population with a range of properties. The device must then be configured from components that are part of that product's platform and manufactured on this flexible line. Robust processes and a comprehensive control strategy interlinked with downstream operations can ensure that every production campaign yields the desired product variant with the correct specifications.

Speed of scale-up has been a long-standing industry concern that could often be addressed with moderate risk-taking by building up an initial capacity based on vetted market assumptions. Even if a manufacturing line for a self-injection device is a complex procurement item that takes, depending on its output, between 1.5 and 3 years to get up and running, staggering the scale-up over time as demand evolves has worked comparably well in the past.

However, as the dynamic growth driven by mass uptake of obesity treatments has shown, this is no longer fast enough. Scale-up needs to take place much more rapidly and demands a bolder approach (i.e. earlier and greater capital layout even in light of uncertain market uptake of the drug).

Figure 2: Ypsomed's platform approach minimises risk, accelerates time-to-market and scales globally – from clinical trials to commercial launch.

At Ypsomed, the thinking has recently been to challenge the assumption that fast-running assembly lines have to be "one trick ponies" geared to manufacture a single product variant. Instead, Ypsomed has considered a more flexible setup that allows the retooling of fast-running lines in acceptable timeframes for other products, thus reducing the risks of building capacity for one single asset (Figure 2). This thought process was driven by different players in the value network and highlights the need for close collaboration within the industry, which has shaped the way that Ypsomed engages with its extended manufacturing ecosystem.

Over the past few decades, a strategic network of partners has emerged, including primary container manufacturers, fill-finish providers and final assembly CMOs. These long-standing partnerships extend across North America, Europe and Asia, supporting both clinical and commercial supply. By working with trusted partners that share aligned quality and performance standards, Ypsomed can complement its own manufacturing footprint with additional capacity and flexibility, ultimately helping to reduce timelines and manage complexity in the development and delivery of combination products (Figure 3).

BUILDING SUPPLY CHAIN RESILIENCE IN A VOLATILE WORLD

While flexible designs and fast, adjustable lines are necessary to address today's supply chain needs for self-injection devices, they are still by no means sufficient. The recent pandemic, the repercussions of the war in Ukraine and the surge in demand due to

"SCALE-UP NEEDS TO TAKE PLACE MUCH MORE RAPIDLY AND DEMANDS A BOLDER APPROACH."

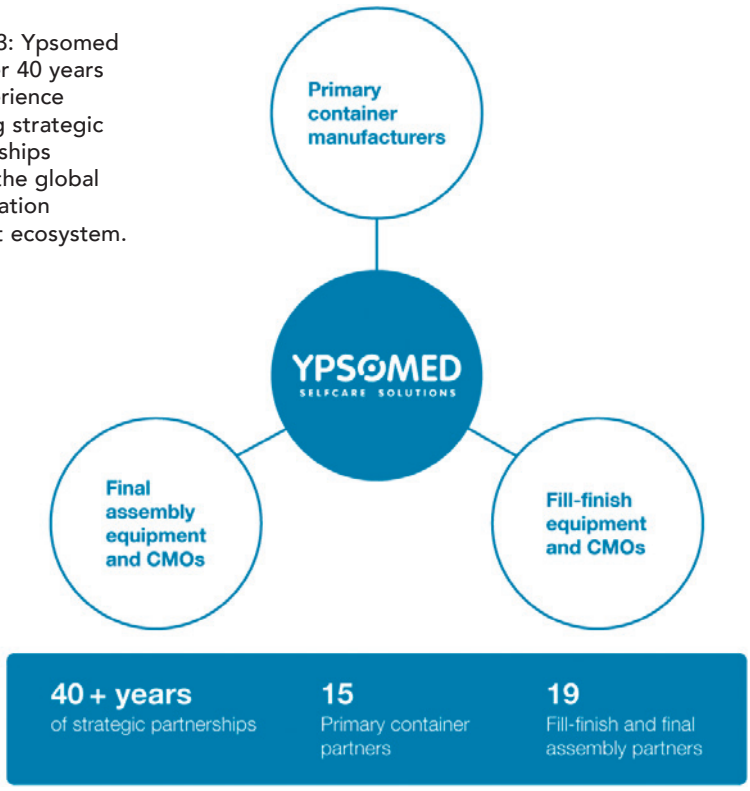

Figure 3: Ypsomed has over 40 years of experience building strategic partnerships across the global combination product ecosystem.

current obesity treatments have highlighted the need for robust supply chains that can cope with rapid change in demand, temporary disruption and shortage of raw materials, components and equipment.

Setting up a resilient and efficient supply chain comes down to balancing redundancy and overcapacity against demand and managing multiple sources of raw materials and components. It can, as a pharma company, be tempting to ask for a fully redundant, geographically distributed supply chain based on equipment from multiple vendors using materials and components from multiple sources.

However, this approach can be unnecessary and rarely yields an economically viable solution for a self injection device. Ypsomed relies on assembly lines with different capacities, usually from different vendors that are located at different sites. In this way, geographic distribution and equipment diversity can be reasonably achieved while ensuring that processes can still be easily transferred, for example, from Ypsomed's leading sites in Switzerland to its new operations in Germany, China and the United States (Figure 4).

"GEOGRAPHIC DISTRIBUTION AND EQUIPMENT DIVERSITY CAN BE REASONABLY ACHIEVED WHILE ENSURING THAT PROCESSES CAN STILL BE EASILY TRANSFERRED."

For single parts, running multiple tools and having sets of pre-qualified cores and cavities ready has been an established approach in the industry for a long time. Instead, the focus is on redundancy rather than diversity, as Ypsomed builds a large share of its tools in its own facility in Burgdorf (Switzerland) and soon in Solothurn (Switzerland).

Figure 4: Ypsomed's manufacturing sites are strategically located to ensure global access and supply chain resilience.

Multiple sources for raw materials and components are much more challenging to put in place. This is especially true for resins, as the purchased quantities are comparably small by global standards and medical grades are not readily available for all resin types. More often than not, it has to be accepted that, at the raw material level, there are no second sources and maintaining a safety stock somewhere in the supply chain is the only practical solution.

The same applies to bespoke components, such as springs and sheet metal parts that are not standard catalogue items. However, in some cases, even if it means lowering the purchased volume per vendor and thus buying with slightly less favourable terms, it might make sense to build up an alternative vendor for such components.

After a period of crises and unprecedented growth, supply chains have been challenged and it is unclear what the future holds, not least with tariffs and trade wars. Combination products are here to stay and will continue to require significant capacity increases to meet the demand fuelled by innovative new biopharmaceuticals, as well as by the next wave of biosimilars.

However, it is an open question as to how multi-dose and reusable devices will develop given the pressure to go carbon-neutral. Are obesity treatments ever growing or subject to the well-known hype-cycle that will see a collapse of demand in the future before stabilising at a steady level? The answers to these questions may be largely unknown, but Ypsomed is confident that, with flexible self-injection platforms, adaptable, geographically distributed manufacturing setups, and equipment diversity and redundancy, the company is well prepared for a broad range of scenarios that may play out in the future.

Philipp Richard

Philipp Richard, Account and Business Development Manager, has been with Ypsomed since 2009. He has worked in various product and key account management roles, collaborating with pharma companies to bring innovative self-injection systems to market. He studied Electrical Engineering at the Federal Institute of Technology (Lausanne, Switzerland). Before joining the world of medical devices, he worked with contactless bearing technology for high-speed turbomachines. Since 2011, he has focused on offering platform-based products and implementing customised injection devices for a growing base of pharma customers. He has managed the transition from project to market supply including ramp-up with several autoinjector customers.

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Interview: SHL Advantec – SHL Medical's New Manufacturing Equipment Sub-Group

In this interview, **Gilbert Fluetsch** discusses the establishment of **SHL Advantec** and the foundation it has built as **SHL Medical**'s in-house equipment specialist. Mr Fluetsch also looks at the role of modular platforms in scaling production and how **SHL Advantec**'s global network is designed to support the changing landscape of medical and pharma manufacturing.

Q To start with, can you give us a brief overview of SHL Advantec and its relations with SHL Medical, a well-established company in the drug delivery space?

A SHL Advantec is a global provider of high-precision moulds and advanced automation systems for the manufacturing, assembly, handling and testing of medical devices and other applications in the wider healthcare sector. Our two core areas of expertise – tooling and automation – originated from SHL Medical's in-house manufacturing capabilities. More specifically, SHL Advantec was formed from the two departments that were responsible for designing and manufacturing the injection moulds, as well as the assembly and testing equipment, for over 90% of SHL Medical's autoinjector and pen injector projects.

SHL Medical is often considered to be one of the pioneers of the autoinjector systems we know today. Specifically, SHL's DAI® autoinjector was one of the most popular autoinjectors on the market for years after its initial commercial launch, laying the foundation for modern self-injection treatment. What some might not realise is that the team now at SHL Advantec has been right there from the beginning of it – working behind the scenes on all of SHL's bespoke and platform devices over the past 20 years. We were the ones designing the low-cavitation moulds, building simple test fixtures and assembly equipment – while, at the same time, pioneering some of the industry's first testing methods. As early as 2002, we had begun developing a semi-automatic testing machine (SATM) for the DAI autoinjector (Figure 1). The first of its kind in the self-injection space, this SATM broke new ground by introducing automation to autoinjector testing.

Figure 1: An SATM developed for SHL Medical's DAI® autoinjector, which saw its first commercial launch in 2006.

"SHL MEDICAL IS OFTEN CONSIDERED TO BE ONE OF THE PIONEERS OF THE AUTOINJECTOR SYSTEMS WE KNOW TODAY."

Today, we are still supporting pharma's growth all the way through to high-volume production. In 2010, SHL Medical set another industry benchmark with the launch of the two-step Molly® autoinjector. When Molly evolved into a modular platform in 2021 – offering greater flexibility in both design and manufacturing – our tooling and automation experts were alongside that journey once again. We didn't just develop the production equipment – we also brought in design-for-manufacturing expertise to ensure that the new platform could scale efficiently, adapt to multiple drug products and meet the evolving needs of pharma customers. These experiences gave us a deep understanding of what it takes to bring reliable, scalable manufacturing solutions to complex self-injection systems. And today, as SHL Advantec, we are carrying that know-how forwards and making our experience available across the medtech and pharma sectors to help more customers solve similar challenges.

Q What led to the decision to create SHL Advantec?

A That decision really came from the market itself. Over the years, we've had a lot of interactions with pharmaceutical companies and, in those conversations, we kept hearing the same thing – that our solutions were right up there with, if not better than, what was available commercially. In fact, some customers even started asking if they could use our equipment for their own production lines, outside of SHL Medical's device programmes. And, the truth is, we were partially doing this already. We have built and delivered final assembly and device testing equipment directly to pharma or their CMO's production sites in Asia, Europe and the US, so working directly with pharma wasn't entirely new to us. What stood out was how consistently those customers came back with positive feedback – not just on the performance of our equipment, but also on the level of support and services we provided. That confidence really made us take a step back and realise that there is a broader market for what we do, even beyond drug delivery devices. That insight is what ultimately led us to establish SHL Advantec.

Q SHL Advantec brings together several businesses, including LCA Automation, SMC Mould Innovation and Superior Tooling, each with its own pedigree. What does bringing them together under one roof unlock?

A Each of these three companies bring decades of experience with them – going back to 1925 in the case of SMC Mould Innovation – so there's a lot of deep expertise there. They've all worked with top pharma and medtech companies, but also operated in other demanding industries such as aerospace, construction and even watchmaking. That diversity really adds to SHL Advantec's strength.

Take LCA Automation for example. LCA has done a lot in the automotive space, which shares the same focus on end-user safety as medical devices, but moves at a much faster pace. Pair that with SHL Advantec's strong foundation in medical quality systems and you start to see the benefit of bringing everyone under one roof. We're already combining that experience, especially in project and quality management, to align our operations across sites. That means more efficient design and development processes, smoother execution and, ultimately, faster, more responsive support for our customers.

Together with these sub-brands, we are building a comprehensive global network across three continents, which lets us optimise supply chains for our customers. What's more, each of these sub-brands can now serve the others' customers across industries. So, whether it's aerospace, pharma, automotive or electronics, the combination of our expertise makes us stronger and more capable of meeting diverse customer needs.

Q How does establishing SHL Advantec as a new sub-group enhance SHL Medical's overall offering?

A Again, it ties back to the global supply strategy. SHL Medical is significantly expanding its manufacturing footprint in the US and Europe. Just this April, it opened its new manufacturing site in North Charleston, South Carolina – its second in the US, alongside the final assembly facility in Deerfield Beach, Florida. On top of that, at least two more facilities are underway, one in Zug, Switzerland, and one in Taoyuan, Taiwan.

With SHL Advantec now operating across the same three continents – with some of our sites just a few hours away from SHL Medical's facilities – we're in a strong position to support SHL Medical's global footprint. That proximity means faster response times and smoother integration between tooling, automation and final assembly – wherever production is happening. In turn, this helps SHL Medical deliver on its promise to its pharma customers with even greater speed and agility.

It's also worth noting that SHL Medical's device technologies are constantly evolving alongside the latest advances in drug development. From the classic DAI autoinjector and the modular Molly platform technology, to the most recent

"WHAT STOOD OUT WAS HOW CONSISTENTLY THOSE CUSTOMERS CAME BACK WITH POSITIVE FEEDBACK – NOT JUST ON THE PERFORMANCE OF OUR EQUIPMENT, BUT ALSO ON THE LEVEL OF SUPPORT AND SERVICES WE PROVIDED."

Gilbert Fluetsch

Vice-President Commercial & Technical Services

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Gilbert Fluetsch is Vice-President of Commercial and Technical Services at SHL Advantec, an SHL Medical sub-group specialising in high-precision moulds and advanced automation for medical device manufacturing. Since joining SHL Medical in 2016, Mr Fluetsch has led engineering teams and driven the development of high-speed assembly and testing systems. With nearly 30 years of experience in the medical device and semiconductor sectors, Mr Fluetsch has held senior roles in engineering, operations and sales across Europe, Asia and the US. He holds an MBA in High Technology Management and a BS in Business Administration.

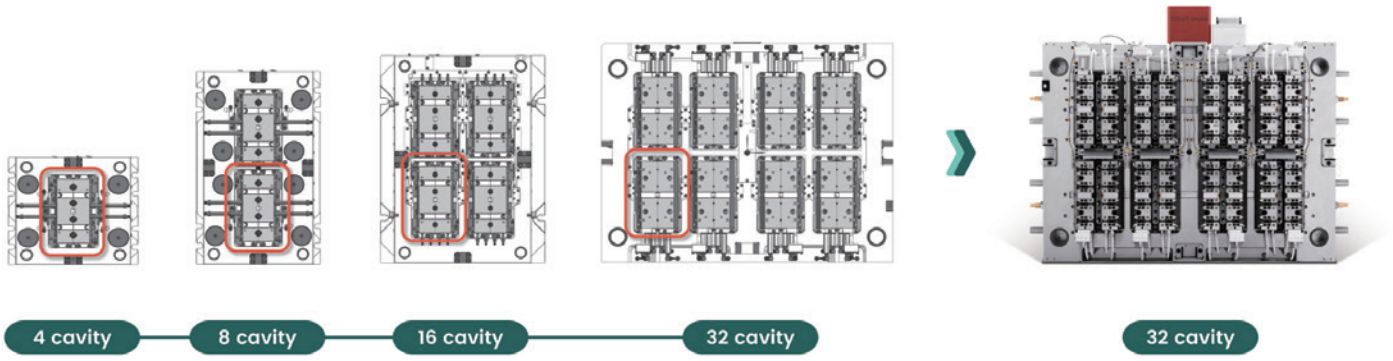

Figure 2: Left: Modular mould inserts with identical stack units in varying configurations. Right: Complete production mould for an autoinjector rear cap.

Elexy™ electromechanical autoinjector, SHL Medical has consistently been ahead of the curve in innovating drug delivery devices. With SHL Advantec now operating as an autonomous entity, SHL Medical has the opportunity to increase its focus on pioneering the next generation of self-injection solutions. And as always, the devices will be supported by cutting-edge equipment solutions by SHL Advantec – now strengthened by the combined expertise of our sub-brands.

Q How does SHL Advantec support the scaling journey, from small-volume clinical or pilot builds through to high-volume commercial production?

A The short answer is "platforms". The longer answer is a bit more nuanced. Much like SHL Medical's autoinjectors, we originally started with highly customised moulds and automation systems tailored to each project. But over time – and through a lot of first-hand experience – we've learned that scaling isn't always linear. A product might start with small clinical batches, then suddenly ramp up if the treatment takes off. Or, as another example, one device design might need to serve multiple drug products, each with slightly different variations in its technical specifications.

From a device perspective, SHL Medical responded with the modular Molly technology by adding an extra level of design and production flexibility to an already powerful platform. From a manufacturing perspective, we also applied modularity into our equipment strategy. We've built up the ability to scale from early clinical runs all the way to full commercial production, without having to reinvent the wheel each time. A good example is our modular mould strategy. These moulds follow a consistent design language but vary in size and cavity configuration (Figure 2). With interchangeable cores, cavities and inserts, we can quickly adapt to different production needs – especially for projects with complex geometries or evolving requirements. This approach cuts down on lead times, lowers costs and adds a layer of manufacturing agility that is essential in today's fast-moving medical landscape.

We've already seen this approach succeed in real-world scenarios. For example, we supported the scale-up of a Molly-based autoinjector used to treat cardiometabolic diseases that was originally forecasted for much lower volumes. As demand grew, we ramped up production by delivering several high-cavitation moulds of up to 48 cavities to SHL Medical's site in North Charleston. That kind of scale-up, done quickly and reliably, really shows the strength of our modular mould strategy in action. And with Superior Tooling being located in North Carolina, we're able to provide more efficient support, ensuring minimal downtime and maximum productivity as production scales up.

Q Can you talk about the SMART platform? What makes it particularly suited to the needs of medical device assembly today?

A The SMART assembly machine is another good example of our modular equipment strategy. The platform was developed to address a key gap in the market – the need for greater flexibility and quality in low- to medium-volume medical device assembly. Traditional manual or semi-automated systems are quicker to deploy but lack the consistency

Figure 3: The SMART assembly machine uses an array of robotic arms that are programmed to migrate device components from feeding systems to moving shuttles.

of full automation. On the other hand, fully automated systems offer high efficiency but typically require long lead times and higher investment, making them less practical for early-stage or high-mix projects.

With drug development accelerating and product pipelines growing, pharma companies need equipment that can adapt quickly without sacrificing quality. That's where the SMART comes in. As a highly modular platform, it combines fully automated handling with standardised stations and interchangeable fixtures, allowing manufacturers to switch between device projects easily while maintaining the reliability and precision of automation (Figure 3). It's an agile, scalable solution built for today's fast-moving medical device landscape, and its value is already being recognised – we've been commissioned to build several new SMART lines set to be installed at sites in both the US and Europe.

Q How early in the process does SHL Advantec typically get involved with pharma or biotech partners, and what kind of impact does that early engagement have?

A Typically, and ideally, we're involved right from the very beginning – at the first interaction between SHL Medical or the device developer and the pharma customer. Early involvement allows us to fully understand the project's technical requirements and recommend the most appropriate path forward, whether that's one of our flexible platforms or a tailored solution.

Early involvement also enables us to take a more integrated approach from the start, bringing together everything from injection moulds and sub-assembly equipment to testing and final assembly systems. This level of co-ordination is where SHL Advantec brings the most value – delivering fully integrated, turnkey solutions that streamline the entire development and manufacturing process.

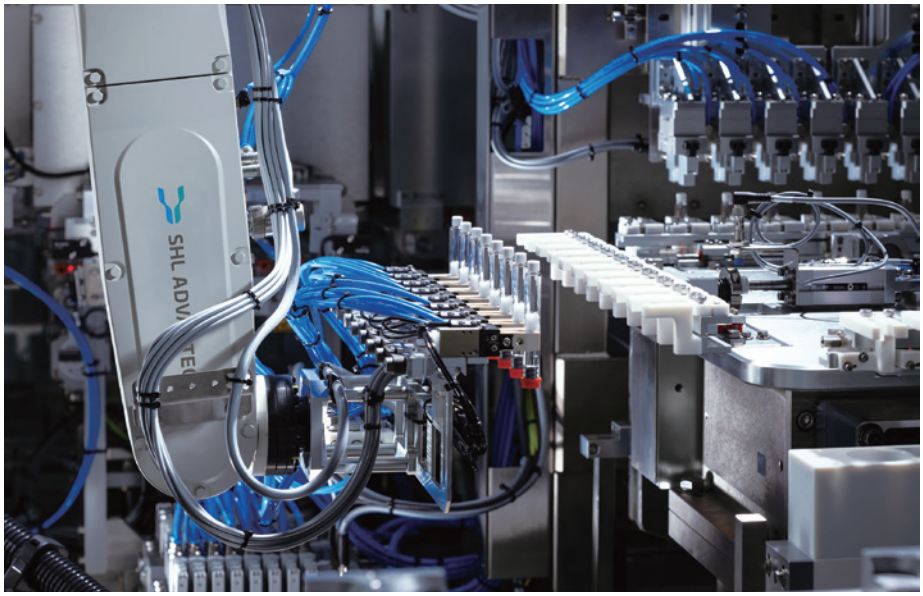

Figure 4: Fully modular final assembly machine with a fully automated primary container loader compatible with both tubs and trays.

Q The drug delivery device industry is experiencing significant shifts, including increased reliance on CDMOs, a push towards onshoring and regionalisation, and a heightened focus on supply chain resilience due to geopolitical pressures. How is SHL Advantec positioning itself in response to these evolving trends?

A These shifts – particularly the growing role of CDMOs and the push for regionalisation – are very much aligned with how we've built our offerings at SHL Advantec. To keep up with the fast-changing pharma landscape, CDMOs need highly flexible equipment that can support multiple device families and quickly adapt to changing project needs. Most of our final assembly and testing platforms were specifically designed with that in mind. They offer modularity, quick project changeovers and the ability to handle any scale of production requirements, from very early-stage pilot production to medium-volume output and extremely high-volume manufacturing, all designed without compromising quality (Figure 4).

Importantly, our equipment isn't limited to devices developed by SHL Medical. Our platforms are designed to be flexible enough to accommodate device projects developed by other companies as well, making them well suited for CDMOs and pharma partners working across a diverse portfolio of drug delivery systems.

We also know that regional compliance is key to speed, which is why our platforms are built to meet varying regulatory and technical standards, such as the EU CE mark and US UL mark, so that they can be deployed efficiently across global manufacturing networks. Whether it's moulding or assembly, our equipment helps customers – and their CDMO partners – move faster, stay flexible and meet market demands with more resilience.

"EARLY INVOLVEMENT ALSO ENABLES US TO TAKE A MORE INTEGRATED APPROACH FROM THE START, BRINGING TOGETHER EVERYTHING FROM INJECTION MOULDS AND SUB-ASSEMBLY EQUIPMENT TO TESTING AND FINAL ASSEMBLY SYSTEMS."

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CDMOs AS STRATEGIC ENABLERS FOR DEVICE INDUSTRIALISATION

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Adam Nightingale of **Springboard**, a **Sanner Group Company**, explores a multitude of approaches to achieving more efficient and sustainable production of medical devices when partnering with a CDMO, and demonstrates the ways in which these partnerships can offer reduced risk and comply with regulations when streamlining industrialisation.

The medical device industry is larger and more innovative than ever. Clinical research is experiencing a surge of innovation in life sciences, with breakthroughs such as cell and gene therapies, personalised medicines, identification of new biomarkers and point-of-care diagnostics. These technological advances not only create exciting opportunities for innovative product development but also introduce new complexities that demand a sophisticated approach to device manufacturing.

Global challenges such as navigating an increasingly complicated regulatory landscape, an overall global lack of manufacturing capacities and high levels of geopolitical uncertainty only add to the complexity of industrialisation. Successfully getting a medical device to market requires an integrated strategy for design and manufacture, which manages risk at each stage of the development process. In this context, the right CDMO is more than a vendor – it can and should be a strategic enabler.

GLOBAL CAPACITY AND FLEXIBLE MANUFACTURING

One of the most critical assets in today's medical device landscape is manufacturing capacity and a flexible global footprint. The surge in demand for glucagon-like peptide 1 (GLP-1) agonists has led to a massive demand for manufacturing capacity from big pharma companies for the devices that deliver them. In turn, this has created a shortage of capacity for other medical

device companies. In particular, the need to produce smaller batches of devices for clinical trials is becoming increasingly difficult, as the capabilities required in terms of agility often differ from those for high-volume production.

Uncertainty regarding the geopolitical situation also implies that medical device companies need to be prepared to be globally flexible. Having partners who can offer suitable manufacturing capabilities in different parts of the world offers resilience as well as improved access to markets. With its worldwide geographical footprint, Sanner Group provides these capabilities and can fulfil diverse customer needs – from regional market launches to globally distributed product lines. Additionally, all manufacturing sites implement the same high-quality approaches and meet the latest global standards such as current GMP, ISO 13485 and ISO 9001 (Figure 1).

CLINICAL MANUFACTURING – CRUCIAL FOR DEVICE COMMERCIALISATION

Clinical builds are critical to the success of a novel product. Device companies and their partners must be prepared to react quickly to new developments, clinical trial findings or regulatory changes. Also, they must have suitable manufacturing systems in place to avoid long set-up delays, which might lead to commercial opportunities being missed. This is where Sanner's new headquarters in Bensheim, Germany, comes into play. The state-of-the-art 10,000m² production facility is designed to be especially scalable and adaptable (Figure 2). The facility features modular bays to support both injection moulding and automated assembly, while also remaining easily reconfigurable based on project needs. Expansion areas are already in place for cleanroom production, high-precision injection moulding and complex automation lines, enabling a quick ramp-up without disruption.

By integrating clinical insights with technical expertise, Sanner can help transform designs into clinically validated solutions positioned for regulatory success and market acceptance. Dedicated experts can identify and resolve design limitations that might impact clinical outcomes. This includes implementing targeted modifications to enhance device functionality, address performance gaps and ensure compliance with evolving clinical requirements. Whether preparing for pivotal trials or addressing post-market performance expectations, cross-functional teams can bridge the gap between innovative concepts and clinical reality. Through iterative prototyping and manufacturing

"THE NEED TO PRODUCE SMALLER BATCHES OF DEVICES FOR CLINICAL TRIALS IS BECOMING INCREASINGLY DIFFICULT, AS THE CAPABILITIES REQUIRED IN TERMS OF AGILITY OFTEN DIFFER FROM THOSE FOR HIGH-VOLUME PRODUCTION."

Figure 1: Sanner has the global manufacturing capacity to fulfil diverse customer needs.

Figure 2: Modular bays allow for quick production ramp-up.

simulations, Sanner can create designs that balance clinical effectiveness with production efficiency. This dual focus reduces clinical trial risks while establishing robust processes for commercial-scale manufacturing.

MANAGING COMPLEXITY WITH INTEGRATED DESIGN AND MANUFACTURING

Developers of medical devices must consider a wide range of factors, including clinical functionality, usability, manufacturability, cost-effectiveness and regulatory requirements. When these considerations are addressed in silos – by different teams and at different times – it can result in an inefficient process with costly redesigns, project delays and elevated levels of technical risk.

Mapping this entire process out as a single programme with an integrated team can provide the foundation for a successful project. From early feasibility and human-centric design through to high-volume serial production, assembly and packaging, each step of the process needs to feed seamlessly into the next. This is achieved by embedding capabilities such as design for manufacturing and assembly, human factors engineering, and regulatory affairs into a development project right from the beginning. Early collaboration can help to avoid late-stage surprises, which can derail timelines and compromise product viability. Hence, building long-term feasibility and scalability into the design itself, instead of adding them as an afterthought, is paramount.

With Design Centres of Excellence in the high-tech hubs of Cambridge, UK, and North Carolina, US, Sanner has access to the highest level of design and development expertise, along with the unique ability to transfer this into cutting-edge medical device manufacturing completely in-house to the manufacturing facilities on three continents.

ACCELERATING INDUSTRIALISATION THROUGH PROTOTYPING

Industrialisation – the process of turning a design into a production-ready product – is often the phase in which projects stall. As already mentioned, the design and product concept must be suitable for reliable high-volume manufacturing from the beginning of the project. Here, iterative prototyping offers a way to reduce technical risk before incurring the high capital investments required for industrialisation.

Technologies such as 3D printing are well-suited for early prototypes. However, representative prototypes of production devices are likely to require pilot moulding. Sanner uses an innovative proprietary change mould system for rapid turnaround of moulded parts and can even 3D-print ceramic tool inserts for "real" parts in a matter of days.

Figure 3: The use of AGVs significantly automates handling and logistics.

> "AUTOMATION SHOULD BE DESIGNED TO MEET THE REQUIREMENTS OF THE DEVICES AND THE INCREASING COMPLEXITY, THE MORE PARTS THAT MUST BE ASSEMBLED."

ADVANCED AUTOMATION FOR QUALITY AND EFFICIENCY

Another aspect that is crucial for efficient industrial-scale manufacturing is automation – not just for speed and cost efficiency, but also for ensuring consistent quality. Automation should be designed to meet the requirements of the devices and the increasing complexity, the more parts that must be assembled. Increased repeatability and the reduction of human errors combined with a higher degree of in-process controls, such as load cells or camera checks, make the highest levels of quality assurance possible.

Using technologies such as automated guided vehicles (AGVs) to transport containers to and from production areas minimises manual handling can reduce the risk of contamination and ensure a clean, safe environment for medical device manufacturing (Figure 3). Automated warehouse systems can optimise logistics and enable efficient inventory management, which is key to ensuring full traceability for a product. Sanner additionally uses virtual reality simulations to enhance the design for assembly process, generating early insights and supporting proof-of-principle studies. This innovative approach optimises seamless scalability to industrial volumes with shortened timelines.

GLOBAL SUPPLY CHAINS AND REGULATORY COMPLIANCE

Supply chain disruption has become one of the defining challenges of recent years. From raw material shortages to transportation delays, these issues can have huge impacts on launch timelines and production continuity. For any global medical device

supplier, it is vital to analyse the resilience of its manufacturing supply chains and put in place suitable mitigations to the biggest risks. As such, Sanner has established a global injection moulding backup system for medical devices. Through a combination of multi-sourcing strategies, local supplier networks, and digital supply chain monitoring, the company offers both agility and security. In addition, Sanner's global footprint allows it to shift production as needed to respond to changing conditions or customer requirements.

At the same time, regulatory compliance and navigating regulatory approval is a core part of any medical device project. Risk mitigation should be proactive, and regulators will expect to see a clear link between the customer requirements and design inputs from the development process and the controls in place during manufacturing. When targeting multiple global markets, a coherent strategy is vital. Sanner has the expertise across Europe, North America and China to support customers through ISO 13485 audits, prepare documentation for CE marking or ensure FDA 21 CFR Part 820 compliance.

FOCUS ON SUSTAINABLE MATERIALS AND PROCESSES

Customers are placing increasing demands on sustainable manufacturing, with sustainability goals now top-level business objectives for multinational medical device companies. Managing this alongside the requirement for many medical devices to be disposable is a considerable challenge wherein both the design of medical devices and their manufacturing must be considered.

Much of the environmental impact of a device is fixed at the design stage by early decisions taken about the product architecture, materials and number of parts, among other factors. Sanner's sustainable design experts apply techniques such as lifecycle analysis to reduce the environmental impact of a design whilst still meeting all user needs. This holistic approach to minimising environmental impact brings in resource efficiency, chemical compatibility and possible alternative materials, as well as the environmental and social impact of raw material extraction, refining, transport and end-of-life disposal. Construction and shape are optimised wherever possible to utilise less resources, and Sanner offers a range of bio-based polymers suitable for some applications.

When it comes to manufacturing, new technologies are reducing the environmental impact of factories and production processes. For example, Sanner's newly expanded Bensheim site features an 18,000 m² roof entirely covered with photovoltaic panels, supplying renewable energy to operations. Beneath the facility, a green oasis provides biodiversity support and natural cooling, helping to regulate the building's temperature in an eco-friendly way. Additionally, three wind turbines supplement the energy mix, ensuring greater independence from fossil fuel sources. These initiatives earned Sanner a Bronze rating from EcoVadis in 2024.

PROOF OF CONCEPT: REAL-LIFE CASE STUDIES

The SmartSite™ IV bag and the needle-free SmartSite™ valve connector, developed by Sanner's US design and development team in close partnership with a key customer, are good examples of sustainable development (Figure 4). The solution addresses the need for empty IV bags, predominantly in in-patient care. As needlestick injuries are a frequent source of injury in hospitals, the bag has a needle-free valve, which eliminates the risk of needle-stick injury during handling. The bags also offer a significant environmental advantage – thanks to their specific design, they can be filled with IV solution, hygienically disinfected and refilled with new medication. This reduces single-use plastic waste considerably. Additionally, they are designed to collapse when emptying to minimise drug waste and save even more resources.

Figure 4: The SmartSite™ IV bag is a good example for sustainable development.

Another example of holistic device industrialisation is the next generation Sentimag system from Endomag, which is used to guide surgeons to the site of breast cancers during surgery. It includes a Sentimag Smartprobe Slim™, which has 50% smaller volume, allowing for easier

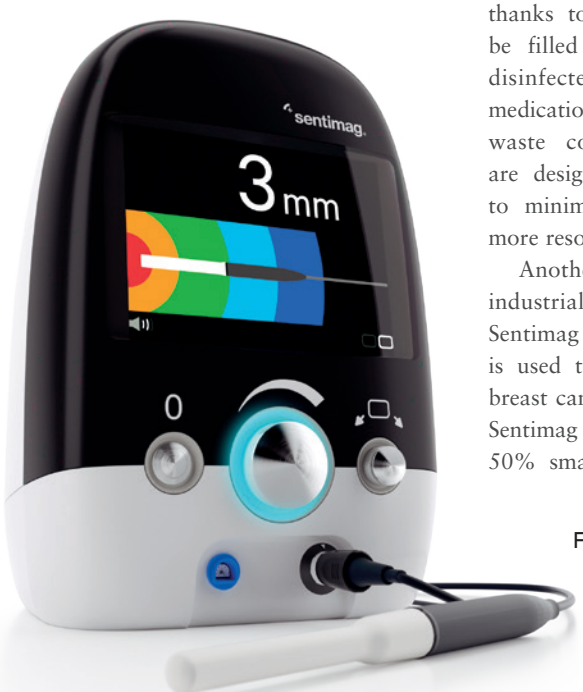

Figure 5: Springboard developed the Sentimag Smartprobe Slim™ for Endomag's next generation Sentimag system.

access and greater visibility, and was developed by the Sanner subsidiary Springboard (Figure 5). This included determining initial feasibility on how to reduce the volume of the probe without compromising the magnetic sensing performance. Following this, different probe concepts were explored around the overall probe size and shape. Springboard produced prototypes of the chosen concept for evaluation by Endomag and then moved to design for manufacture. Production-equivalent probes served for verification testing. The system was approved by the US FDA in January 2023. This case study shows how Sanner can support clients from development to design transfer and beyond. In the future, the company can also produce these devices in its new state-of-the-art manufacturing sites in Europe and the US.

CDMOs AS STRATEGIC ENABLERS FOR DEVICE INDUSTRIALISATION

The pressure on the medical device industry is intensifying – from manufacturing shortages, global geopolitical uncertainty and supply chain risks to an increasingly complex regulatory landscape. By combining world-class design expertise, global manufacturing capacity, regulatory insight and operational excellence, Sanner helps its partners not only to navigate these challenges but to thrive within them.

Whether launching a next-generation combination product with a new drug delivery device, an innovative diagnostic or a connected health device, Sanner provides everything pharmaceutical companies need from a single source. As healthcare continues to evolve, so too must the partnerships that drive it. With a foundation of quality and shared purpose, Sanner is ready to meet the future of medical device development together with its customers and partners.

Adam Nightingale

Adam Nightingale, Quality Manager at Springboard, a Sanner Group Company, is a Chartered Engineer with a background in Mechanical and Manufacturing Engineering. He has worked on medical devices from early-stage R&D all the way through to mass production and has a broad range of experience, including in drug delivery devices, surgical devices and diagnostics. Mr Nightingale leads development projects through design transfer and is responsible for the quality systems at Sanner UK.

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SHORTENING AND DECARBONISING THE INHALATION SUPPLY CHAIN

Louise Righton of **Bespak** examines the potential for reducing emissions across the pMDI supply chain, considering the localisation of suppliers to shorten supply chains as well as strong partnerships for developing novel, low-carbon alternatives to current high-emission pMDI manufacturing processes.

Maintaining the supply of critical medicines in the face of a changing world poses a growing challenge. From natural disasters and geopolitical events that disrupt supply chains to the increasing pressure to reduce greenhouse gas emissions, there is a clear need to optimise the production and supply of life-saving drugs and devices. Localising supply chains where the option exists, reducing emissions throughout the process and supporting the development of lower carbon products and drug delivery devices, are the key steps that Bespak, a specialist CDMO in the inhalation space, is already taking.

THE TEMPESTUOUS CLIMATE-HEALTHCARE FEEDBACK LOOP

When considering the future of drug delivery, the interplay between healthcare and the environment cannot be ignored. There are clear negative impacts of climate change on health – a key example being the impact of pollution on respiratory conditions – and yet, healthcare itself contributes significantly to pollution and greenhouse gas emissions.[1]

> "WHEN CONSIDERING THE FUTURE OF DRUG DELIVERY, THE INTERPLAY BETWEEN HEALTHCARE AND THE ENVIRONMENT CANNOT BE IGNORED."

The ever-evolving supply of vital medicines is enormously complicated and is therefore also vulnerable to disruption. For instance, there have been significant increases in the number of potential supply issue alerts raised in the UK between 2021 and 2023 due to various geopolitical factors.[2] Taking this into account, factors such as extreme weather events – increasing in severity and frequency due to climate change – pose an even greater threat to supply security.

With the health of the planet so inextricably linked with the health of the population, there is a clear and urgent need to decarbonise the value chains within healthcare systems. To this end, in the UK, the NHS has committed to becoming "carbon net zero" – a significant step given that it currently accounts for 4–5% of the UK's total carbon emissions.[3] Approximately 60–70% of this total is from supply chains across all operations – highlighting the importance of considering the full ecosystem, including aspects such as raw materials sourcing, processing, packaging and transportation.

Therefore, by working to shorten these supply chains – through more local sourcing rather than global value chains – emissions can be limited, while simultaneously building up more resilience to extreme climate-induced weather events and other disruptions. The scope of these changes is significant and different sectors must approach this in different ways. Within the pharma industry, CDMOs have a central role to play because of their connections across all stages of drug development and commercialisation, and their deep, often niche, industry expertise.

CONSIDERING THE INHALATION SUPPLY CHAIN

In the UK, around 25% of NHS carbon emissions are from medicines. Whilst the majority of these emissions result from the manufacture, distribution and use of medicines (20%), pressurised metered dose inhalers (pMDIs) alone are responsible for 3%.[4] This is due to the high global warming potential (GWP) of the propellant gases currently used in these devices. Reducing these emissions is not just a moral obligation for producers – evolving regulations have highlighted pMDIs as an area of focus, putting pressure on the inhalation supply chain to decarbonise.

"WITHIN THE PHARMA INDUSTRY, CDMOs HAVE A CENTRAL ROLE TO PLAY BECAUSE OF THEIR CONNECTIONS ACROSS ALL STAGES OF DRUG DEVELOPMENT AND COMMERCIALISATION, AND THEIR DEEP, OFTEN NICHE, INDUSTRY EXPERTISE."

In fact, due to the evolving regulations impacting high-GWP propellant gases used across various industries, the supply chain will likely shrink, resulting in propellant scarcity and price increases before phasedown targets are close to being met for pMDIs. With this in mind, it is key to establish the capabilities and processes for manufacturing with the next generation of propellants and, in so doing, take opportunities to strengthen and decarbonise the entire supply chain. This will allow the industry to continue to provide patients with access to their familiar and trusted medicines whilst minimising harm to the planet.

Achieving this will require concerted efforts from manufacturers and suppliers, with collaborations and consortiums offering a promising approach to bringing about large-scale, industry-wide improvements. As a specialist inhalation CDMO, Bespak is well positioned to foster these collaborations and make a significant contribution to consortiums – such as through membership of the International Pharmaceutical Aerosol Consortium (IPAC) and associated group IPAC-RS (on Regulation and Science). These connections can help to drive wider efforts towards carbon reduction and engage players from across the value chain, both for pMDIs specifically and for other inhaled drug-device combination products going forward.

STRATEGIC LOCAL COLLABORATIONS TO SHORTEN THE SUPPLY CHAIN

Partnering with suppliers that are working towards the same goals, or have the capabilities needed to enable these goals, can accelerate progress – for example, streamlining the transition to low-GWP propellants in pMDIs. Prioritising working with local suppliers adds further benefits of shortening the supply chain and increasing resilience of supply.

With this goal in mind, Bespak has collaborated with several local partners in the UK to streamline its processes for developing and manufacturing with both of the new, low-GWP propellants:

- Drawing on a longstanding partnership, Bespak worked with DH Industries (Basildon, UK) – expert pMDI processing and packaging engineers – to optimise manufacturing equipment for the new propellants.
- Valuable insights and guidance on safe propellant handling have been developed through close collaboration with Orbia Fluor & Energy Materials (Runcorn, UK), a global provider of fluoroproducts and technologies, and supplier of low-GWP propellant, HFA-152a. Likewise, Bespak partnered early with Honeywell, a company driving decarbonisation in refrigerants, and supplier of HFO-1234ze, to facilitate early adoption of this near-zero GWP solution for its customers.
- Canisters for pMDIs are supplied by H&T Presspart (Blackburn, UK), a specialist in devices and components. Through collaboration, Bespak and H&T Presspart accelerated the development of a GMP clinical-scale facility for supplying pMDIs manufactured with HFA-152a, closing a gap in the global supply chain for the adoption of low-GWP propellants in pMDIs.

These collaborations have focused on enabling the transition to low-carbon pMDIs, so bringing all the suppliers into the conversation is hugely beneficial for optimising the components and manufacturing processes needed to succeed in the propellant switch. Harnessing the collective technical expertise of all key

players drives faster progress in product development and manufacturing readiness. Furthermore, because the majority of these businesses are based in the northwest of England, this creates a strong cluster of expertise in the region and supports local sourcing, minimising transport-related emissions. And, because they are aligned with the ultimate goal of enabling low-carbon pMDIs, the various constituents of the supply chain work together more cohesively.

Similarly, Bespak has partnered with other specialist businesses in the region to support the full drug-device development pathway. This includes collaborations with contract research organisations (CROs) such as OzUK (Chippenham, UK), whose independent laboratory supports an efficient formulation feasibility and development pathway for pMDIs, and the Medicines Evaluation Unit (Manchester, UK), which is working to accelerate clinical trials of products using the new generation of propellants.

These collaborations enable knowledge sharing of low-carbon pMDI technology and processes, helping to increase the pace at which new low-carbon pMDIs can be developed and clinically evaluated. Accelerating this pathway can allow the industry to adopt low-GWP propellants more quickly, whilst also bolstering regional expertise, bringing the entire process – from formulation through to commercial supply – into the UK and ultimately shortening the supply chain.

Work is already ongoing towards the low-GWP pMDI transition. Additionally, the partnerships and principles built here will help to inform best practices for inhaled and nasal drug-device combination product development and manufacturing more widely.

"TRANSITIONING TO LOW-GWP ALTERNATIVES IS LIKELY TO BE THE MOST SIGNIFICANT OPPORTUNITY TO REDUCE OPERATIONAL EMISSIONS."

"COLLABORATIONS ENABLE KNOWLEDGE SHARING OF pMDI TECHNOLOGY AND PROCESSES, HELPING TO INCREASE THE PACE AT WHICH NEW LOW-CARBON pMDIs CAN BE DEVELOPED AND CLINICALLY EVALUATED."

ESG PRINCIPLES ACROSS THE SUPPLY CHAIN

As outlined above, strategic partnerships and co-location can help to foster a supply chain that works together to bring low-carbon drug-device combination products to patients efficiently. For many drug developers and manufacturers operating in the pMDI space, current propellant gases make up a significant proportion of their total emissions, and therefore transitioning to low-GWP alternatives is likely to be the most significant opportunity to reduce operational emissions. However, there will always be room to go further.

Bespak has recently shared its inaugural ESG Update which sets out its holistic environmental, social and governance (ESG) strategy. This considers, amongst other issues, the lifecycles of its products – identifying opportunities for improvement at all points in the value chain. This means consideration of Bespak's internal processing operations, as well as those of its raw material suppliers and service providers.

To achieve reductions in carbon impacts, Bespak is partnering with its suppliers to determine how to use more sustainable materials and identify opportunities to minimise resource consumption and waste from the earliest stages of product development. For example, Bespak has recently investigated the reductions in emissions associated with a switch from synthetic to bioethanol in production processes.

Another approach is lifecycle assessments (LCAs), which are useful tools for understanding the cumulative environmental impacts of the energy and materials that go into products and identifying key areas for improvement. Bespak has recently conducted its first LCA on its BK357 pMDI valve platform, which has been independently verified by expert sustainability scientists from Tunley Environmental (Leeds, UK) in line with ISO 14067:2018 standards. Steps such as this are key parts of Bespak's work towards designing products with full lifecycle considerations in mind.

Taking a full business-level view of environmental impact is also critical

Louise Righton

Louise Righton is Head of Strategic Marketing at Bespak. She has worked in the pressurised metered dose inhaler (pMDI) industry for more than 20 years in global marketing, commercial and government affairs roles. A graduate in Industrial Management, a Chartered Marketer and a Fellow of the Chartered Institute of Marketing, Ms Righton also holds a master's degree in Strategic Marketing Leadership. She is a board member at the International Pharmaceutical Aerosol Consortium and is committed to leading the change to sustainable pMDIs.

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for effecting sustainable change. Bespak has committed to fully and transparently mapping and communicating its environmental footprint across Scope 1–3 emissions and will submit its Science Based Targets initiative (SBTi) targets for validation in 2025, working with expert sustainability advisors at The Carbon Trust (London, UK).

Additionally, in Bespak's first year as a standalone company, a double materiality assessment (DMA), in alignment with the requirements of the European Sustainability Reporting Standards (ESRS), was conducted. To gain a full picture of all potential impacts, risks and opportunities (IROs) associated with business operations, this was followed by value chain mapping from upstream raw material sourcing to downstream patient use, identifying key segments, activities and stakeholders at each stage. Stakeholders were then engaged to consider the detailed insights collected across various sustainability topics. Each sustainability matter was reviewed with a focus on identifying relevant IROs before being scored to arrive at the final DMA. The results of the 2024 DMA assessment were used to define Bespak's key ESG focus areas and form the foundation of its sustainability strategy.

With all of these sustainability initiatives in mind, co-ordinating change across the supply chain requires commitment and leadership. Having ESG principles built in from the start, Bespak is well placed to drive this change and to help encourage and enable decarbonisation across the inhalation industry.

CONCLUSION

Shortening and decarbonising the supply chains of medicines will be vital activities in achieving the long-term sustainability of healthcare – particularly in inhaled drug delivery. Taking steps to reduce emissions through process optimisation, the development of lower carbon options and more local sourcing and collaboration will be an important approach for pharma. In the inhalation sector, Bespak is working to lead this approach, with collaborative partnerships that span the value chain, helping to streamline the path to low-carbon pMDIs for its partners. In a world of change, a willingness to collaborate has never been more important and Bespak is proud to lead the way.

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FINDING COMMON GROUND: FACTORS FOR ESTABLISHING AND SAFEGUARDING SHELF LIFE IN COMBINATION PRODUCTS

Lauren Orme of **West Pharmaceutical Services** discusses the regulatory considerations that need to be taken into account when designing combination products. She reviews the essential testing and standards required for both drug and device when establishing their shelf life and storage in a combined product.

For more than half a century, combination products have opened up new and more effective treatment pathways by integrating drugs into complementary delivery platforms. The first combination products, such as antibiotic-loaded bone cements and drug-eluting stents, emerged in the 1970s to lay the foundations for continued advances in materials engineering and drug delivery technology, which prompted significant market growth.[1]

Indeed, the global annual volume of prefilled syringes alone is estimated currently at around five billion units, with this sector of the market projected to be worth more than $35.7 billion by the end of 2031.[2]

Where the components of drug and device come together as combination products, whether co-packaged or developed as a single entity, they can bring significant benefits to patients. This is particularly true in the face of rising chronic disease indications, with combination products either simplifying self-administration or easing the treatment burden by enabling drugs to be delivered without the intervention of a medical professional, and often in a home setting.

Making these benefits a reality, however, requires manufacturers of combination products to consider and align a range of critical variables. A key area of consideration is storage and shelf life, given the fundamental requirement for a combination product to function safely, effectively and as intended when it reaches the point of use. The shelf life of a combination product can be influenced by

"A KEY AREA OF CONSIDERATION IS STORAGE AND SHELF LIFE, GIVEN THE FUNDAMENTAL REQUIREMENT FOR A COMBINATION PRODUCT TO FUNCTION SAFELY, EFFECTIVELY AND AS INTENDED WHEN IT REACHES THE POINT OF USE."

various environmental factors including, but not limited to, temperature, humidity, light exposure and pressure. The evaluation of each environmental factor must then be considered during the combination product's transportation, storage and use.

Therefore, establishing robust shelf-life and stability studies is crucial to the combination product development process and a fundamental requirement for regulatory submissions. Shelf-life requirements are defined by global consensus standards and country-specific regulations. In the case of sterile products, container closure integrity studies will also be required to show that packaging components fulfil their responsibility of maintaining a sterile barrier, and ensuring that the product continues to be protected from contamination, defects or damage. The resulting data from those studies allows accurate labelling information to be established, defining the expiration date.

REGULATORY LANDSCAPE

Globally, findings from well-defined shelf-life studies are vital to provide regulators with evidence to substantiate the labelled storage conditions for the entirety of a product's stated shelf life. At a practical level, when conducting compliance studies, manufacturers are led by several global consensus standards and widely accepted guidelines from the US FDA, WHO, EU EMA, US Pharmacopoeia (USP) and International Council for Harmonisation (ICH).

For medical devices, widely recognised standards such as ISO 11607, which specifies requirements for real-time ageing of the packaging system, and ASTM d4169, which defines the testing needed to evaluate shipping and transportation,[3,4] play critical roles. In addition, ISO 14971 requires full evaluation of the risks present throughout all phases of the lifecycle of a medical device "from the initial conception to final decommissioning and disposal". Similarly, on the drug side, USP <1207.1> emphasises evaluation of container closure integrity throughout "anticipated storage, shipment, and distribution environment".

In Europe, the European Medical Device Regulation (MDR) 2017/745 – which replaced the Medical Device Directive (MDD) 93/42/EEC in 2021 – does not explicitly define shelf life, but does include a series of requirements that outline expectations. For example, Annex I, General Safety and Performance Requirements, GSPR 6, states: "*The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.*"[5]

In the US, device shelf-life expectations are detailed in FDA Guidance on Shelf Life of Medical Devices.[6] These rules define shelf life as the term or period during which the device remains suitable for intended use.

For drug manufacturers, both the US and EU rely on the ICH guidelines, which dictate that formal stability studies should be carried out in accordance with risk management processes, including both long-term and accelerated tests. These guidelines underscore the importance of study controls, including a prescribed stability protocol that contains specific product information, environmental conditions (temperature and humidity) and specified tolerances. These studies provide objective evidence of the period during which a drug product is expected to remain within the approved shelf-life specification, provided that it is stored under the conditions defined on the container label.

Furthermore, the USP provides comprehensive guidelines for drug stability, underscoring the importance of validated testing methods, suitable environmental conditions, packaging and microbiological integrity. It defines stability as: "*The extent to which a product retains, within specified limits, and throughout its period of storage and use, i.e., its shelf life, the same properties and characteristics that it possessed at the time of manufacture.*"[7]

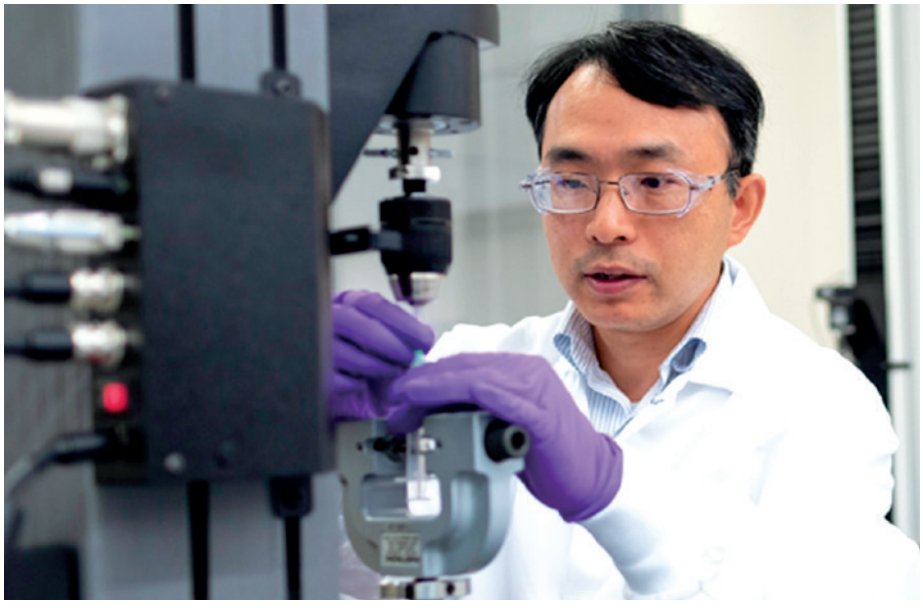

Figure 1: The journey to a robust drug product testing programme starts with the components, through preclinical trials and Phase I of the drug development process.

Although USP provides its own guidelines, it often aligns with other regulatory documents, such as those of the FDA and ICH, ensuring broad compliance.

Overall, the inherent complexity of combination products requires manufacturers to develop holistic shelf-life studies that meet the regulatory requirements of both drug and device, while also considering the latest consensus standards and guidelines. All of this emphasises the need for manufacturers to develop scientific, risk-based approaches to ensure product reliability and patient safety (Figure 1).

ESSENTIAL GUIDELINES: CONDUCTING EFFECTIVE STUDIES

When determining shelf life, it is crucial to consider the interaction of all constituent elements – drug, device and packaging – not only in isolation but also in terms of how they will function together as a combination product. Studies should be designed to assess all aspects that support the final combination product requirements and label claim. If this includes multiple conditions (for example, temperature ranges of 2–40°C and humidity ranges of 15–85%), it may be necessary to conduct multiple studies in parallel to fully cover the claimed range. It is quite possible that each element will have differing shelf-life characteristics. As such, once they have been independently established, there is a need to identify the threshold levels that are common to all elements. These lowest common denominator values will ultimately dictate the final shelf-life claim for the combination product as a whole (Figure 2). Therefore, it is critical to ensure alignment between drug and device manufacturers on the data needed to establish the combination product shelf life (e.g. labelling, expiry).

Both functionality and integrity are key areas of focus in the evaluation of factors that could influence shelf life.[8,9] When it comes to functionality, products will be assessed as to whether time, use or environmental conditions lead to a compromise in their ability to meet all performance requirements. For example, for drug delivery devices, essential drug delivery outputs (EDDOs) and primary functions should also be considered as part of shelf life. There must also be an assessment of their effects on the sterile barrier, drug stability and container closure integrity (CCI) as per USP <1207> "Package Integrity Evaluation – Sterile Products".[10,11]

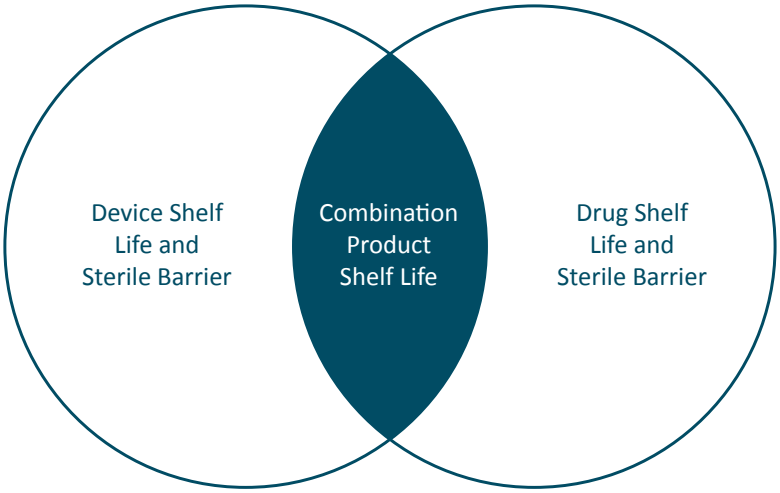

Figure 2: Identifying common shelf-life characteristics between drug and device.

When generating data to support shelf life, both accelerated and real-time studies can be beneficial to support the overall data package. While real-time data are expected for drug product submissions, most regulatory bodies will accept accelerated data to support medical devices for the initial shelf-life claim, with the expectation that real-time studies are being conducted to confirm the claim.

Significant study controls must be in place for this data to be deemed sufficiently valid. For example, to ensure that results reference equivalent products and batches, studies should be conducted on the "to-be-marketed" version of the product. As such, all processing activities including manufacturing, materials and packaging should be identical to those of the final combination product. Where any differences exist, strong scientific rationales should be generated to provide justification of study validity.

Consideration must also be given to the fact that studies are conducted using qualified, calibrated and validated chambers capable of maintaining the tolerances specified in industry consensus standards. Examples of such tolerances include ±5°C for freezer conditions of -20°C; ±3°C for refrigeration conditions of 5°C; ±2°C for ambient conditions above 8°C; and ±5% for humidity testing at any temperature.

Importantly, for shelf-life studies to be truly robust, it is critical to consider not just testing the finished product based on final storage conditions but also to evaluate the potential areas that could negatively impact its performance to function as intended throughout its entire lifecycle. Supply chains will all differ in terms of the various stages involved and storage conditions must be considered at every stage, from manufacturing to sterilisation, co-packaging and distribution. Therefore, it is critical to review the supply chain in detail and ensure that studies are conducted to represent the process appropriately.

Since multiple stakeholders are likely to be involved, including distributors and importers, quality agreements should

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be used to outline roles, responsibilities and obligations to ensure compliance with the previously defined storage conditions based on shelf-life requirements. It is only through such an integrated approach that manufacturers can be sure that shelf-life claims will be upheld all the way throughout the supply chain to the patient.

With multiple actors and variable factors to consider, the complexity of establishing and supporting combination product shelf-life claims becomes increasingly apparent. Far from being regarded as a linear list of tasks to be completed, it demands a highly integrated approach, where the characteristics of interlinked elements are considered, and all parties are collectively aligned on critical parameters dictated by high-integrity data.

West's direct experience of working with pharmaceutical partners on shelf-life studies has underlined how this process can be enhanced and accelerated by adopting a holistic, data-driven approach. The company's comprehensive, consultative support in this area covers everything from strategic planning to stability studies, and is underpinned by extensive knowledge of the latest regulatory standards to ensure that labelling claims are robust and fully substantiated. These are services that form part of West's wider approach to proprietary and non-proprietary combination products, which is backed by its deep understanding of primary packaging components and systems, and a broad, integrated offering that includes in-house analytical testing as well as services relating to clinical development and regulatory compliance.

Lauren Orme

Lauren Orme, Senior Director of Regulatory Intelligence and Policy, West Pharmaceutical Services, ensures regulatory compliance by overseeing monitoring of global regulatory requirements, changes in regulatory landscapes and implementation of compliant, validated labelling. She has over 20 years of experience in the pharmaceutical packaging, medical device and analytical services industries. Prior to her current role, Ms Orme held technical roles in global analytical services and commercial to support customers with education and adoption of West's products and services. Ms Orme earned a BS in Biology from West Chester University (PA, US). She is certified as a Project Management Professional.

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Interview
Phillips Medisize Grows its Capabilities with Vectura

In this exclusive interview with ONdrugDelivery's Guy Furness, **Brian Thompson** and **Dave Thoreson** of **Phillips Medisize** discuss the company's expanded capabilities as a result of its recent acquisition of Vectura, bringing extensive expertise and experience in the inhalation sector within the global CDMO. The discussion covers how Phillips Medisize organises its global operations, the opportunities that the acquisition of Vectura represents and where the company goes next.

Q To start us off, could each of you briefly introduce yourselves and your roles at Phillips Medisize, and could you also touch on what was exciting to you about Phillips Medisize's recent acquisition of Vectura?

"WITH THE ACQUISITION OF VECTURA, WE'VE BROUGHT IN EXPERTISE AND CAPABILITIES IN THE PULMONARY FIELD FROM AN ENGINEERING AND A SCIENTIFIC PERSPECTIVE."

BT I'm Brian Thompson and in my role, I'm responsible for our scale-up capabilities across our 23 manufacturing sites around the globe, as well as our programme organisation. With respect to the Vectura acquisition, I'm really excited about being able to pair the complementary skillsets of Vectura's deep knowledge of the inhalation space and Phillips Medisize's expertise in scale manufacturing. Likewise, their expertise in inhalation formulation is a capability that we can leverage to help support our customers. By combining these skillsets we are increasing the value we can bring to our customers.

DT I'm Dave Thoreson, Vice-President of Global Operations, and I'm responsible for new product introduction (NPI) across Phillips Medisize. I've been with the organisation for over 27 years, so I've seen the company through a number of transitions with different ownership, and I've been very engaged in the acquisition of Vectura. In my role, I have responsibility for the manufacturing operations across Phillips Medisize, so I'm involved in building the equipment and tools we use, getting those validated and truly industrialising and moving projects into a production setting. Brian and I work very closely on that.

Regarding the Vectura acquisition, Phillips Medisize has been in the drug delivery device space for a long time, including some activity in the inhalation space. With the acquisition of Vectura, we've brought in expertise and capabilities in the inhalation field from an engineering and a scientific perspective that really gives us that strong foothold in inhalation. This is going to complement our existing development, NPI and manufacturing capabilities. We're excited to have that.

The other aspect to consider is our R&D or the development capability that we offer to our customers. We have our main sites in Hudson (WI, US) and Sturer (Denmark), as well as R&D design centres in India, China and across the world. Vectura expands our ability to meet our customers where they are. Our customers engage with us along the whole value chain, and we don't really determine where they're going to connect with us. Our

Brian Thompson
Senior Director, Global New Production Introduction & Programme Management

Brian Thompson leads the global NPI and programme management capabilities at Phillips Medisize. He has 25 years of experience in pharmaceutical and medical device product development and commercialisation. Mr Thompson joined Phillips Medisize in 2017 and holds bachelors' degrees in Chemistry and Biochemistry, and an MBA from the University of Minnesota (Minneapolis, MN, US).

spectrum of capabilities runs from early phase all the way to commercial manufacturing and lifecycle management, and Vectura will accelerate our growth with combination formulation science, device technology and inhaled drug development expertise.

Q How are you using Phillips Medisize's global network of manufacturing sites and its single quality management system (QMS) to help customers build locally, cut logistics costs and still give them true global design freedom?

BT As Dave mentioned, we have the breadth of expertise and capabilities to meet a customer wherever they are in the product lifecycle, and, with Vectura, that includes the inhalation space. If they're ready for product development, no matter what development phase a customer is in, we can support them. If they need supply for clinical trials, we can help develop that product all the way through from early development through all clinical phases. If they're ready for high-volume device manufacture, we can bring them into one of our 23 global operation sites. With those capabilities and our global footprint across North America, Europe and Asia, we can also meet them wherever they are geographically to develop their products, scale their products and, ultimately, deliver to their patients in those regions.

DT Our goal is to be able to act as a true full-service CDMO for our customers (Figure 1). We want to be able to support the moulding, producing the sub-assemblies, final assembly, handling the drug, packaging – everything our customers could need. With the acquisition of Vectura, we're now also developing the capability to help with formulation, especially in inhalation. In injectables, where we're more established, we handle the drug, but we've not offered inhalation formulation services before, so we're excited to move into that area.

Dave Thoreson

Vice-President of Global Operations

As Vice-President of Global Operations, Dave Thoreson has responsibility for all commercial manufacturing operations and NPI engineering functions for Phillips Medisize. He collaborates with customers to ensure that the company's manufacturing locations, capabilities and quality systems are aligned with customer expectations and compliant with US FDA regulations and current GMP. Mr Thoreson joined Phillips Medisize in 1996 as a project manager at its Phillips (WI, US) operation. He was promoted to Engineering Manager in 1999 and then moved to the Menomonie (WI, US) facility as Engineering Manager in January 2003. In February 2005, Mr Thoreson was promoted to General Manager of the Phillips Medisize Menomonie medical site and, shortly thereafter, Vice-President and General Manager. In that role, he was responsible for the sales and operations of the medical sites (including Ireland) that support the Phillips Medisize medical business. In 2019 he was promoted to his current role as Vice-President of Global Operations. Prior to joining Phillips Medisize, Mr Thoreson was employed by SSI Technologies. He holds a BS degree in Manufacturing Engineering.

As it relates to the QMS, Cheryl Norder, our Vice-President of Quality and Regulatory, has been with the organisation a long time as well. She's done an excellent job of fully integrating what we call our design capabilities, as well as NPI, where we're involved with industrialising a product. Wherever we are in the world, it's really a global set of standards that we're executing, whether it be in R&D,

"WE CAN MEET THEM WHEREVER THEY ARE GEOGRAPHICALLY TO DEVELOP THEIR PRODUCTS, SCALE THEIR PRODUCTS AND, ULTIMATELY, DELIVER TO THEIR PATIENTS IN THOSE REGIONS."

Figure 1: Across 23 global manufacturing sites and seven R&D locations, Phillips Medisize offers a full suite of CDMO services across the entire product lifecycle.

NPI or sustaining operations. That provides us with a really differentiated capability within Phillips Medisize.

Q How do you choreograph a project when, for example, design starts in Denmark, clinical builds run in Wisconsin and commercial-scale manufacturing lands in Suzhou – and still keep a single source of truth for design history files?

BT That's an interesting example of a combination – it's not a specific one we have going on, but we often deploy our global capabilities and footprint for a programme. We have one programme running right now that's actually using all of our R&D capabilities around the globe to execute it. As a medical device CDMO, quality is deeply embedded in our vision, values and culture, which manifests in our products and solutions.

The choreography you mentioned is critical to ensure that we have that quality. In addition to our global QMS, we also have a global enterprise resource planning system, global programme management processes, and a global design and development process that we deploy. We also share common transfer and scale-up processes. We call the combination of these systems "Advanced Quality Planning".

And we also use common metrics and measures to execute on our programmes at the local level. We use common processes and systems in a common language that helps us communicate and ensure success for our programmes. We also have centrally managed teams of programme leaders and technical experts that are positioned around the globe so that they can integrate with our programmes, teams, customers and site capabilities wherever they happen to be.

DT Each programme is a little different in what the customer needs. As Brian mentioned, we have our programme management process where we can deploy our various project teams to those needs. It depends on the capability that that programme needs at the time. It's really about bringing the right people to

"WE HAVE CENTRALLY MANAGED TEAMS OF PROGRAMME LEADERS AND TECHNICAL EXPERTS THAT ARE POSITIONED AROUND THE GLOBE SO THAT THEY CAN INTEGRATE WITH OUR PROGRAMMES, TEAMS, CUSTOMERS AND SITE CAPABILITIES WHEREVER THEY HAPPEN TO BE."

the table and making sure that we have the right capabilities on the team. Then once we start to move towards manufacturing, we can put it in the location that best supports the customer's full supply chain.

Q Phillips Medisize offers both proprietary devices and CDMO services for its customers' own products, can you go into how you combine these two aspects of the business?

BT I think we're well positioned with our innovative platform offerings alongside having a full capability to develop and manufacture bespoke devices to meet the needs of our customers fully. If they're looking to reduce cost, accelerate time to market or lower risk, then, if our platform products are a suitable match for their drug, that can be a way to enter the market with that sort of structure. On the other hand, if they have a novel therapy that needs a bespoke solution to deliver their drug or to service their patients, then we can help them through that journey, too. That can be from the very early proof-of-concept phase all the way through scale manufacturing. It really just depends on what creates the most value for our customers – we take a very customer-centric approach and want to make sure that our offerings create the most possible value for them.

DT If a customer's product is going to be a blockbuster pharmaceutical, it's probably going to be a bespoke product. Other customers, if they're targeting generics or smaller markets, might want to leverage a platform or one of our platform technologies. Once again, we view it as a full set of capabilities that we can reach into and deploy as best fits the needs of our customers.

Q I was at RDD Europe in Lisbon in May and that conference was the first time Vectura appeared under the Phillips Medisize banner, signalling the full merger. What capabilities have you already unlocked between Vectura's formulation know-how and your device-manufacturing scale, and how will future projects feel different for a pharma or biotech company that brings you on board next quarter?

"DEPENDING ON THE PRODUCT WE'RE WORKING ON, WE'RE GOING TO PUT THE RIGHT TEAM ON IT AND VECTURA IS A MAJOR ADDITION TO WHAT WE CAN OFFER."

DT Vectura brings us a comprehensive swath of capabilities and experience in the inhalation space. Depending on the product we're working on, we're going to put the right team on it and Vectura is a major addition to what we can offer. What the acquisition has really done, and what our customers will likely find, is that we've closed a gap in our capabilities and we'll be even more able to adapt to whatever their needs might be wherever they are in the development process.

BT Vectura has over 350 employees and they bring decades of experience in the inhalation combination product development space with them. Currently, we're still in the early parts of our journey to really understand all of their capabilities and experience and what they can bring to our pharmaceutical partners. I think of it in terms of complementary skillsets, experience and capabilities, and there's a process to discovering how both sides optimally fit together. In time, Vectura will be fully integrated into Phillips Medisize.

We can now say to our customers in the inhalation space that we can take a project from discovery all the way through to delivery by combining those skillsets, with Vectura added to Phillips Medisize's expertise. In the past, I believe that Vectura would need to work with third parties to scale and manufacture their products – now we can help support that under the Phillips Medisize umbrella.

Q Looking to the future, what do you see as Phillips Medisize's next strategic moves in terms of growth and investment?

DT There are always going to be capabilities that we don't have that we want invest in, so we're going to look for those – whether in medtech, diagnostics or drug delivery. Next, I would say we are evaluating capabilities and organic and inorganic growth options that would benefit our customers and expand our scale.

As part of Molex, and part of Koch, we can either do that organically, where we win contracts, we develop programmes and we continue to build scale, or we can do that inorganically, where we can go out and identify a region that we're not in, a capability that we don't have or a scale that we need to continue to grow into and focus resources into.

We have our current global footprint, which we've done a lot of work to optimise, and we're well positioned to continue to grow it within the regions we're currently in. However, we will also look into other regions we're not currently established in, so that we can offer the best possible support to our customers. We take a very long-term view and will continue to scale accordingly.

BT I'll add that the industries we serve as a CDMO are evolving rapidly, so the other area that we will continue to invest in is in our people. We need to attract, develop and retain the best people, who can create the technology, capabilities and expertise that our customers and patients will need in the future.

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Expert View

HARNESSING X-RAY AND AI FOR A NEW ERA OF QUALITY CONTROL

Dr Richard Parmee of Sapphire Inspection Systems discusses the multitudinous applications of X-ray inspection technology for high-speed pharmaceutical production lines, covering the value of introducing artificial intelligence and machine learning techniques to enhance detection and improve safety.

"ALL THESE ISSUES – AND MORE – ARE NOW BEING ADDRESSED BY A NEW GENERATION OF X-RAY TECHNOLOGY THAT CAN DO SO MUCH MORE THAN DETECT A FRAGMENT OF METAL OR GLASS IN A DRUG CONTAINER OR AUTOINJECTOR."

Patients and healthcare professionals take it for granted that there will be one tablet in each cavity of a blister pack when they open a new box of drugs – and that they will all be the tablets described on the packaging. However, for pharma manufacturers, it is no mean feat to ensure that there are no extra, missing or incorrect tablets in a sealed blister pack on a high-speed production line.

Products containing multiple tablet formulations that are to be taken at different times add to the complexity for manufacturers. Other everyday challenges where the stakes are high include checking for dangerous air bubbles in a prefilled drug-device combination product, such as an insulin pump, and ensuring that the needle of an autoinjector is in the correct position. All these issues – and more – are now being addressed by a new generation of X-ray technology that can do so much more than detect a fragment of metal or glass in a drug container or autoinjector.

HIGH SENSITIVITY AND HIGH RESOLUTION

The latest X-ray systems combine low-energy X-ray imaging with active pixel sensor (APS) technology to achieve high sensitivity, with resolutions 10 times greater than traditional end-of-line X-ray machines. This means that these machines can detect not only missing or broken tablets (Figure 1), with an inspection zone created around each tablet pocket, but also contaminants, such as metal, even though the products are packaged in metallic foil blister packs. X-ray technology can even detect paper inside cardboard by using adaptive algorithms to check that each box contains an instructions for use (IFU) leaflet to ensure regulatory compliance (Figure 2).

X-ray technology can also be used to check the mass of a product, such as to ensure that the dose carriers for powder

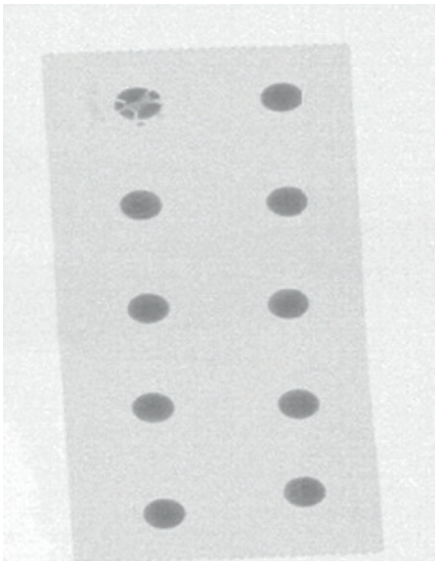

Figure 1: A broken tablet in a blister pack.

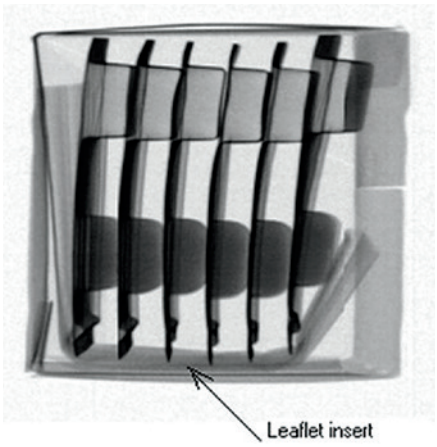

Figure 2: Checking for the presence of an IFU leaflet.

inhalers meet the therapeutic dose limits or confirm that containers of common over-the-counter medications meet the necessary weight requirements. It can also check the individual masses of a series of items within a pack, enabling it, for example, to detect and reject an underweight bottle of cough syrup in a multipack, even if some of the other bottles contain slightly

too much medication. Another potential functionality is to verify the number of products, such as syringes, in a sealed multipack. Furthermore, it can provide an elemental analysis to differentiate tablets with different formulations.

Foreign body detection has always been crucial for formulations in drug containers. The new generation of X-ray inspection equipment can detect metal or glass particles with diameters as small as 0.1 mm, which would not be visible to the naked eye on a high-speed production line. Image processing software now provides the tolerance levels required to deal with the variable shape and thickness of glass containers. The technology can cope with tapered shapes, ridges and bulges, enabling it to detect tiny shards of glass within a glass vial – as well as confirming that the container is filled to the correct level. The presence of potentially dangerous bubbles in a vial or ampoule of liquid medicine can also be detected.

QUALITY CHECKS

As medical devices become ever more complex, the latest technology can also perform quality checks on drug delivery devices such as autoinjectors (Figure 3), ensuring that the needles are in the correct position and that other parts of the device mechanism are within position tolerances. In-line inspection machines are automatically fed and motorised on different axes so that the autoinjectors can be rotated for the required quality checks.

The technology can even cope with the challenge of subcutaneous osmotic insulin pumps, where the drug is packaged in a hollow titanium rod where it is vital there are no bubbles, which could cause the flow of insulin to be interrupted. The radiography is challenging as it involves inspecting organic material with air voids through a machined titanium enclosure. However, techniques such as mechanical stabilisation and combining multiple image sets can be used to enhance the feature contrast.

Packaged dressings containing silver salts, which provide anti-microbial properties, are another example of where the latest X-ray inspection technology can help manufacturers. In this case, it provides a way of checking the presence and assay level of these elements on the production line, as well as ensuring that the contents are correctly positioned within the packaging.

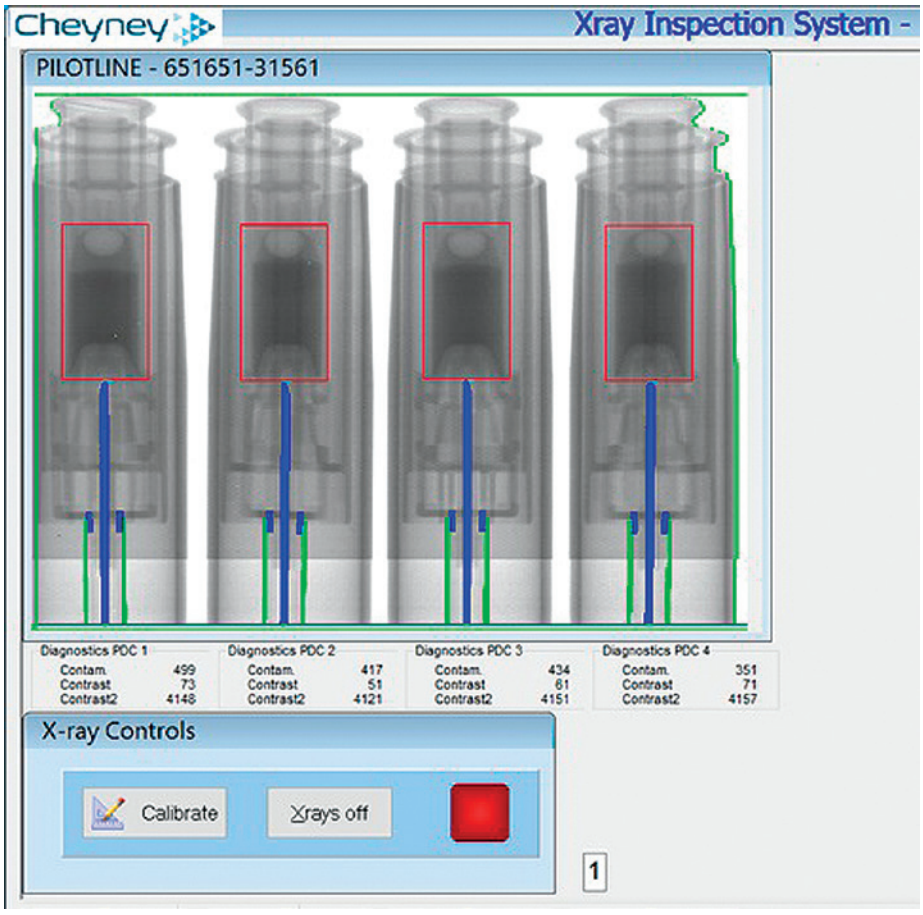

Figure 3: Checking the position of autoinjector needles.

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING

Until now, automated inspection systems have generally used rule-based algorithms, which require skilled software resources and substantial testing. However, with the advent of artificial intelligence (AI) and machine learning (ML), X-ray imaging can be combined with AI-based algorithms so that manufacturers can automate the training and defect detection processes with unparalleled accuracy.

AI algorithms, particularly those based on ML and computer vision, are trained to recognise patterns and anomalies within X-ray images. Once trained, these algorithms can rapidly analyse large volumes of images and flag potential defects, such as foreign bodies, locations, voids, misalignments or other irregularities that might otherwise go unnoticed. This automation not only reduces human error but also speeds up the inspection process, resulting in higher throughput and lower production cost.

"ONCE TRAINED, THESE ALGORITHMS CAN RAPIDLY ANALYSE LARGE VOLUMES OF IMAGES AND FLAG POTENTIAL DEFECTS, SUCH AS FOREIGN BODIES, LOCATIONS, VOIDS, MISALIGNMENTS OR OTHER IRREGULARITIES THAT MIGHT OTHERWISE GO UNNOTICED."

"AI AND X-RAYS CAN CONTRIBUTE TO SAFER WORKING CONDITIONS BY AUTOMATING INSPECTION PROCESSES AND REDUCING THE NEED FOR HUMAN WORKERS TO INTERACT WITH POTENTIALLY DANGEROUS EQUIPMENT."

PREDICTIVE MAINTENANCE

Maintaining equipment and machinery in optimal working condition is essential for minimising downtime and avoiding costly repairs. Predictive maintenance is an area where AI and X-rays are proving to be game changers. Traditionally, maintenance approaches rely on scheduled service intervals, often leading to unnecessary downtime or missed opportunities to address emerging issues.

By combining X-ray imaging with AI, pharma manufacturers can implement predictive maintenance strategies that allow for real-time monitoring of machinery components. X-rays provide detailed insights into the condition of critical parts, while AI analyses the data to predict when a part is likely to fail. This enables companies to perform maintenance only when it is truly needed, avoiding unplanned breakdowns and reducing the costs associated with unnecessary repairs.

For example, AI-powered X-ray systems can be used to monitor the structural integrity of critical components, ensuring that wear and tear are detected before they lead to failure. This proactive approach to maintenance increases operational efficiency and extends the lifespan of machinery and equipment.

WORKER SAFETY

Worker safety is a paramount concern in manufacturing environments, especially when dealing with heavy machinery, hazardous materials or complex assembly processes. AI and X-rays can contribute to safer working conditions by automating inspection processes and reducing the need for human workers to interact with potentially dangerous equipment.

AI algorithms can process X-ray images and identify high-risk areas where failure is likely. By identifying and addressing these risks early, pharma companies can prevent accidents and protect their workers from harm. Moreover, by automating routine inspections, AI and X-rays can reduce the exposure of workers to harmful radiation, toxic substances or dangerous machinery – further contributing to a safer workplace.

INTEGRATION TO TRANSFORM MANUFACTURING

The integration of AI and X-rays in manufacturing and production is set to transform the pharma industry. By automating critical tasks and providing real-time insights into the condition of materials, machinery and products, this powerful combination allows manufacturers to achieve higher efficiency, reduce costs and maintain competitive advantages.

As AI and X-ray technology continue to evolve, their impact on the manufacturing landscape will only grow. And, with millions of patients relying on their medication every day, that represents a helping hand for pharma manufacturers when it comes to ensuring that each dose is right the first time – every time.

ABOUT THE COMPANY

Sapphire Inspection Systems develops X-ray inspection technology, applying its patented technology and advanced stochastic algorithms to deliver optimal speed, sensitivity and sophistication of detection. As well as designing bespoke X-ray inspection systems, Sapphire also provides a wide range of standard X-ray inspection systems to cater for hundreds of different products in the pharmaceutical, food and cosmetics industries.

Dr Richard Parmee

Richard Parmee, PhD, is Founder and Chief Executive Officer of Sapphire Inspection Systems, an X-ray inspection technology specialist. As well as designing bespoke solutions, Dr Parmee and his team provide a wide range of standard X-ray inspection systems to cater for hundreds of different products in the pharmaceutical, food and cosmetics industries.

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Expert View

MASTERING COMMERCIAL MANUFACTURING FOR STERILE INJECTABLES

Jennifer Gattari of Pfizer CentreOne delves into what is required to succeed at the commercial phase of sterile injectable manufacturing, going on to explore the challenges that companies can expect and the critical strategies that can help ensure a smooth and scalable journey to market.

The sterile injectable (SI) market is entering an exciting era of growth and opportunity. Valued at approximately US$732 billion (£543 billion) in 2023, it is projected to nearly double, reaching $1.4 trillion, by 2030.[1] This surge is being fuelled by key trends, including the rise of glucagon-like peptide 1 (GLP-1) therapies, the continued momentum behind biologics and biosimilars and an increasing demand for patient-centric delivery options, such as prefilled syringes (PFS) and autoinjectors.

As these therapies progress toward commercialisation, the path forwards becomes more intricate. Complexities, such as managing evolving regulatory expectations and maintaining sterility at larger scales, mean that moving an SI from late-stage clinical success to commercial readiness takes more than good intentions — it takes careful strategy backed by deep technical expertise and flexible capabilities.

AN EXCITING NEW ERA FOR STERILE INJECTABLES

The SI market is entering a dynamic and transformative period, energised by breakthrough advancements across the pharmaceutical and biopharmaceutical industries. Demand for SIs is being fuelled not only by the rise of complex therapies targeting chronic and rare diseases but also by a shift in how medicines are delivered to patients. As the SI sector grows, it brings new opportunities to address long-standing health challenges, as well as new expectations for manufacturing agility, regulatory compliance and patient-centric innovation.

> "AS THE SI SECTOR GROWS, IT BRINGS NEW OPPORTUNITIES TO ADDRESS LONG-STANDING HEALTH CHALLENGES, AS WELL AS NEW EXPECTATIONS FOR MANUFACTURING AGILITY, REGULATORY COMPLIANCE AND PATIENT-CENTRIC INNOVATION."

Figure 1: A key trend complicating SI scale up is the variety of patient-centric delivery formats that must now be accounted for, such as PFS and autoinjectors.

"EVEN SMALL DEVIATIONS DURING FILLING, CAPPING OR INSPECTION PROCESSES CAN COMPROMISE PRODUCT INTEGRITY, RESULTING IN POTENTIAL BATCH REJECTIONS, COSTLY INVESTIGATIONS OR LOSS OF SUPPLY."

Several key trends are transforming the segment:

- **The Expansion of Biologics and Biosimilars:** Biologics continue to lead the market's expansion, offering precision therapies for complex diseases where conventional, small-molecule treatments often fall short. Alongside them, biosimilars are helping to broaden access to life-changing medicines by providing cost-effective alternatives, encouraging greater adoption across healthcare systems worldwide.
- **The Rise of GLP-1 Therapies:** Originally developed for Type 2 diabetes, GLP-1 analogues are now demonstrating remarkable potential in obesity management. With the global GLP-1 market forecast to grow from $37.4 billion in 2023 to $471.1 billion by 2032, these therapies are poised to become a defining force within the SI landscape, offering new therapeutic options for a growing global health challenge.[2]
- **A Focus on Patient-Centric Delivery:** There is a growing emphasis on patient-friendly delivery formats, particularly for therapies requiring frequent or long-term administration. Advances in drug formulation and device technology are enabling more complex therapeutics such as biologics to be delivered through convenient platforms, including PFS, cartridges and autoinjectors, to enhance ease of use and safety for patients managing chronic conditions (Figure 1).

CRITICAL MANUFACTURING CHALLENGES ON THE PATH TO COMMERCIAL SUCCESS

While the advances and rising trends in the SI space are creating exciting opportunities for patients and healthcare systems, they are also bringing new challenges to the commercial manufacturing process, which is already inherently complex. The shift from development to commercial-scale SI production presents a distinct set of operational and technical demands, requiring process reliability, as well as rigorous control over sterility, compliance and infrastructure.

Navigating Regulatory Complexity

The regulatory landscape for SIs has always been complex, but it's become significantly more demanding in recent years. Updates to global standards, such as the revised EU GMP Annex 1, have introduced heightened expectations for contamination control, environmental monitoring and aseptic processing across manufacturing sites.

At the same time, combination products are introducing further hurdles. These therapies fall under dual regulatory oversight, often requiring companies to demonstrate compliance with both pharmaceutical and medical device standards, such as 21 CFR Part 820, ISO 13485 and region-specific guidance for device components. This dual oversight increases the depth and breadth of regulatory obligations, particularly around areas like device validation, human factors engineering and data integrity.

Maintaining Sterility at Commercial Scale

Sterility assurance becomes even more complex as production scales from clinical to commercial volumes. Fill-finish operations must maintain precision across larger batch sizes, requiring rigorous process controls and comprehensive environmental monitoring programmes. Additionally, many of the advanced biologics moving through pipelines today are highly sensitive to temperature, shear forces and oxygen exposure.

These are all factors that can be amplified during commercial-scale manufacturing. Even small deviations during filling, capping or inspection processes can compromise product integrity, resulting in potential batch rejections, costly investigations or loss of supply. Achieving consistent sterility at scale demands not only robust manufacturing practices but also an in-depth understanding of each product's unique handling and process sensitivities.

Meeting Advanced Equipment and Facility Requirements

Manufacturing the next generation of SI products often requires investments in specialised equipment and facility upgrades. For many complex or highly potent drugs, such as GLP-1 agonists, traditional cleanroom designs are no longer sufficient. Facilities must now incorporate isolator-based technologies, flexible fill lines capable of handling multiple device formats and advanced automation and digitisation solutions to ensure consistent aseptic conditions.

In many cases, adapting existing infrastructure to meet these demands involves significant capital investment and detailed technical planning. Without the right upgrades and flexibility built into production lines, companies may face compatibility issues, longer tech transfer timelines and constraints that limit future scalability.

NAVIGATING COMMERCIAL MANUFACTURING WITH CONFIDENCE

The challenges involved in commercial SI manufacturing are significant, but they are also surmountable. As therapies become more complex and regulatory expectations more demanding, success at scale depends on the ability to anticipate risks, adapt quickly and maintain rigorous control without sacrificing efficiency.

With the right approach in place, pharmaceutical and biopharmaceutical companies can build the resilience needed to navigate this complexity. The following strategies reflect some of the most important considerations for companies looking to scale commercial manufacturing successfully and sustainably in today's evolving landscape.

"EARLY, THOROUGH GAP ANALYSES ARE CRUCIAL TO HELP UNCOVER MISMATCHES BETWEEN SENDING AND RECEIVING SITES, SUCH AS EQUIPMENT DIFFERENCES, FACILITY DESIGN VARIANCES, PROCESS PARAMETER TOLERANCES AND DOCUMENTATION GAPS."

Take a Structured, Risk-Based Approach to Tech Transfer

Commercial success starts with a well-executed tech transfer. For SIs, this process demands far more than simply replicating development-stage processes at commercial scale; it requires a detailed, risk-focused mindset from the outset. A structured, backwards design approach, beginning with the final critical quality attributes (CQAs) needed for patient safety and product efficacy, helps guide the transfer planning.

Every element, from material flow to environmental controls, must be evaluated to ensure that what works at the development scale can be consistently and reproducibly achieved at commercial volumes. Early, thorough gap analyses are crucial to help uncover mismatches between sending and receiving sites, such as equipment differences, facility design variances, process parameter tolerances and documentation gaps. Addressing these proactively can reduce the risk of deviations, delays and unexpected reworks that can disrupt commercial readiness.

Additionally, understanding the product's sensitivity to environmental stresses, such as temperature, oxygen exposure or agitation during filling, must be incorporated into transfer planning. Identifying and mitigating these potential risks early on not only protects sterility and product quality but also strengthens readiness for regulatory inspections, where tech transfer robustness is often closely scrutinised.

Embed Regulatory Thinking from the Outset

Achieving regulatory compliance in SI manufacturing is not about reacting to expectations after processes are established; it requires proactive integration of regulatory principles at every stage of scale-up and commercialisation. A practical approach starts with embedding regulatory experts into cross-functional project teams early.

Involving experts early ensures that facility designs, aseptic processes and environmental control systems are aligned with current standards from the outset, such as the revised EU GMP Annex 1 and new requirements on the horizon. Regulatory insights should shape the development of contamination control strategies, cleaning validation approaches and equipment qualification protocols, rather than being retrofitted later, when changes are far more costly and disruptive. For combination products, developing a clear regulatory roadmap detailing how quality management systems will address both drug and device requirements can reduce ambiguity and prevent delays during submission and approval.

Another best practice is to design manufacturing and validation documentation with inspection-readiness in mind. This includes building robust audit trails, ensuring data integrity across all critical control points and structuring validation master plans to align with evolving expectations. Validation activities should demonstrate that processes meet predefined specifications, as well as clearly document risk-based rationales for process parameters and environmental controls, reinforcing the quality risk management principles that regulators increasingly expect to see.

Build Flexibility into Sterility Assurance at Scale

Maintaining sterility becomes considerably more complex as batch sizes increase and production moves toward commercial volumes. Scaling up SI manufacturing

amplifies operational risks, from the impact of faster line speeds on fill precision to the greater difficulty of consistently maintaining environmental controls across larger production windows.

To mitigate these risks, manufacturing processes must be designed with scalability and flexibility in mind. Stress-testing fill-finish parameters at commercial-representative scales is critical. This includes validation of key variables, such as fill volume consistency, container closure integrity and line speeds. Products that are sensitive to temperature, light, oxygen exposure or shear forces require additional process controls and real-time monitoring to safeguard CQAs.

Invest In the Right Infrastructure, Not Just the Biggest

Achieving commercial readiness for SIs often hinges on facility and equipment capability. As product pipelines increasingly include high-potency biologics, lyophilised drugs and patient-centric formats such as PFS and cartridges, manufacturing environments must evolve beyond the limits of traditional cleanroom spaces.

Adapting or designing facilities to support this complexity means making deliberate investments in fit-for-purpose technologies. Isolator-based filling lines can significantly reduce contamination risk compared with traditional open systems, supporting enhanced sterility assurance in line with evolving regulatory expectations. Flexible fill lines capable of handling multiple container types and volumes enable manufacturers to accommodate both liquid and lyophilised presentations without extensive revalidation, improving operational agility.

"ADAPTING OR DESIGNING FACILITIES TO SUPPORT THIS COMPLEXITY MEANS MAKING DELIBERATE INVESTMENTS IN FIT-FOR-PURPOSE TECHNOLOGIES."

The goal is not simply to scale, it is to scale intelligently. Facilities and equipment that are purpose-built to align with the specific requirements of the product portfolio are far more likely to support successful, sustainable commercial supply. Investing early in the right infrastructure protects product quality, accelerates launch timelines and reduces the risk of costly retrofits or remediation down the line.

BUILDING SUSTAINABLE SUCCESS IN SI MANUFACTURING

As SI therapies continue to evolve, the path to commercial success will only become more complex. Manufacturers that prioritise risk-based planning, embed regulatory alignment early, build resilient supply models and invest in the right infrastructure will be best positioned to meet future demands with confidence. Working with a CMO that applies these strategies, along with proven experience in SI scale-up, regulatory compliance and flexible manufacturing, can make the difference between a challenging launch and a seamless, sustainable commercial supply. In an environment where precision, agility and reliability are vital, partnering with the right CMO can help companies navigate complexity and deliver breakthrough therapies to the patients who need them most.

ABOUT THE COMPANY

Pfizer CentreOne is an award-winning CMO, powered by Pfizer's technical expertise and global network. Pfizer CentreOne offers commercial manufacturing for oral solids, sterile injectables and biologics – delivering scale, quality and process excellence.

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Jennifer Gattari

Jenny Gattari, Global Business Development Lead at Pfizer CentreOne, has more than 30 years of experience across manufacturing, supply chains, R&D and business development in the pharmaceutical field. As part of her role, Ms Gattari is responsible for identifying and securing new business opportunities for Pfizer's contract manufacturing business. Starting her career in manufacturing, Ms Gattari's passion for delivering life-changing results for patients across the globe propelled her transition into R&D. In this role, she led the launch of a successful clinical chemistry and immunoassay analyser for chronic diseases. Having held distinguished positions at Abbott, Hospira and Pfizer, she has been instrumental in building a global network, devising investment strategies, creating profitable product pipelines and mentoring up-and-coming academics for Pfizer's community programme.

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Expert View

PRESSURE ON THE SUPPLY CHAIN: TARIFFS, REGULATIONS AND TRANSPARENCY

Jacob Tyson at IMed Consultancy and **Jon Lawrence** at JAGGAER consider the changes in the regulatory landscape for medical device manufacturers; the critical role that suppliers, distributors and importers play in ensuring effective post-market surveillance; and the technologies that companies are adopting to support traceability solutions.

"MANUFACTURERS NEED TO COLLECT, ANALYSE AND ACT ON A MUCH WIDER RANGE OF POST-MARKET DATA, MAINTAINING TRANSPARENCY IN DATA ACQUIRED THROUGHOUT A DEVICE'S LIFECYCLE."

The burden on medical device manufacturers is increasing with new tariffs on key components, such as polymers and steel, taking effect in the US, as well as regulatory frameworks such as the EU Medical Device Regulation (MDR), the *In Vitro* Diagnostics Regulation (IVDR) and the UK's Statutory Instrument, which require more stringent post-market surveillance (PMS). In particular, manufacturers may find themselves stuck between a rock and a hard place as their usual suppliers are subjected to increasing costs, while regulators also increase the requirements surrounding PMS and extend them to ongoing, systematic procedures to monitor the real-world safety and performance of medical devices, as well as the safety and reliability of the supply chains involved in their production.

Now, manufacturers need to collect, analyse and act on a much wider range of post-market data, maintaining transparency in data acquired throughout a device's lifecycle. By monitoring user feedback and adverse event reports, makers of drug delivery devices – such as insulin pumps, transdermal drug patches, metered dose inhalers, implantable infusion pumps and autoinjectors – can make data-driven decisions to improve product design, provide updated training or issue safety communications. These devices interact closely with patients and often operate autonomously, increasing the potential for unnoticed failures or misuse.

These new requirements call for tools and practices to help businesses collect the data from both suppliers and device end users that will enable them to achieve this kind of 20:20 vision. If effectively collected and analysed, these data can become a treasure trove for device design improvements, supporting manufacturers' efforts to identify possible risks early on, improve sustainability and usability, and meet new emerging regulatory standards across the world.

This mindset shift calls for manufacturers to expand their focus on direct product performance and hone in on their supply chains. In the US, as a 10% flat tariff hits medical device manufacturers sourcing components from abroad, a seismic rethink of the supply chain is in order. Devices that include chips may be particularly affected by semiconductor tariffs, as will drug delivery devices and implants that rely on medical-grade polymers – such as polypropylene and polyethylene – and high-grade metals such as titanium and stainless steel, which are mostly imported from China, India and Southeast Asia.

Insulin pumps often include polyurethane, polycarbonate (PC) and silicone for their tubing and reservoirs, for example, while transdermal patches – which administer drugs through the skin, including nicotine and hormones – use polymers such as ethylene vinyl acetate, polyethylene, silicone and acrylates to ensure skin adhesion and controlled drug diffusion. Drug-eluting stents employ polymers such as poly(lactic-co-glycolic) acid, polycaprolactone and polyethylene-co-vinyl acetate to deliver therapeutic agents, such as sirolimus, directly to arterial walls while offering controlled biodegradation. Finally, prefilled syringes for biologics and vaccines use advanced materials such as cyclo-olefin polymer and PC, which ensure chemical inertness and clarity.

Suppliers, distributors and importers play a key role in ensuring effective PMS and, as supply chains are redesigned due to market pressures, it is critical that

"A MORE COMPLEX PICTURE IS PROVIDED BY 3PL DISTRIBUTORS, WHO ARE RARELY CONSIDERED WHEN IT COMES TO ESTABLISHING TRANSPARENCY AND ACCOUNTABILITY FOR PMS DATA COLLECTION."

manufacturers ensure that they engage with providers that are able to meet their own obligations under the EU MDR and IVDR. Suppliers, distributors and importers also need to maintain complaint registers and collaborate with authorities in case of recalls or potential non-conformities. To date, the contractualisation of PMS reporting duties is rarely requested by manufacturers, but as supply chains need to be reviewed, it is critical that this important aspect is not overlooked.

The legal requirements concerning reporting for importers, distributors and authorised representatives include the obligation to co-operate to achieve an appropriate level of traceability.[1] Distributors specifically are required to keep a register of complaints, non-conforming devices, recalls and withdrawals.[1]

In addition to these, the European Authorised Representatives and UK Responsible Persons – local representatives for companies without a physical location in the EU or UK, respectively – must meet their own specific set of legal requirements. They must, for example, verify that technical documentation meets regulatory standards, maintain copies of essential compliance documents and liaise with competent authorities in case of safety concerns or incidents.[1]

A more complex picture is provided by third-party logistics (3PL) distributors, who are rarely considered when it comes to establishing transparency and accountability for PMS data collection. Despite their grassroots role in delivering devices to hospitals, care homes or directly into the hands of users, they are rarely contractually asked to collect and report storage conditions, transport times or complaints received.

As more and more stakeholders gather and handle critical data for PMS, it is clear that the systems and processes required to interpret and store this information also need to evolve. To keep up with this demand, businesses are increasingly turning to advanced artificial intelligence (AI) and machine learning technologies that support traceability solutions, while also offering automation and real-time visibility across the entire supply chain. Sharing demand forecasts, for instance, helps both manufacturers and suppliers to optimise production processes – minimising waste, lowering operational costs and, subsequently, reducing prices.

These technologies provide powerful tools to formalise supplier collaboration, such as by incorporating explicit clauses in contracts that obligate suppliers and 3PLs to contribute actively to PMS activities. This includes responsibilities such as sharing customer feedback, reporting product complaints and providing critical data for safety evaluations.

In addition to helping formalise partnerships with efficient contractual agreements, these technologies can enhance data sharing by establishing robust, real-time communication channels among all stakeholders. This enables faster identification and resolution of potential risks. Automated data collection further strengthens this process by reducing reliance on manual entry, minimising human error and ensuring the availability of accurate and timely information.

Moreover, new algorithms can be used to drive predictive analytics, identifying trends and anomalies within data that may signal potential supply chain disruptions or quality concerns. This capability allows manufacturers to take pre-emptive action, thereby maintaining regulatory compliance and ensuring patient safety. Enhancing supplier collaboration is therefore critical

"NEW ALGORITHMS CAN BE USED TO DRIVE PREDICTIVE ANALYTICS, IDENTIFYING TRENDS AND ANOMALIES WITHIN DATA THAT MAY SIGNAL POTENTIAL SUPPLY CHAIN DISRUPTIONS OR QUALITY CONCERNS."

to achieving a whole host of benefits that go beyond PMS compliance.

Tariff pressure, the UK's new PMS Statutory Instrument and the EU Directive on Liability for Defective Products all provide a clear call to action to review contractual agreements with suppliers, which should be reshaped to form mutually beneficial partnerships for the safeguarding of patient safety and industry growth.

ABOUT THE COMPANIES

Founded in 2012, **IMed Consultancy** offers a wide range of expert services to the global medical and health technology industry. The company supports medical device and *in vitro* medical device manufacturers to drive innovation and improve patient care and outcomes worldwide, providing assistance through all stages of the product lifecycle from concept and design through clinical studies and post-market surveillance.

JAGGAER specialises in enterprise procurement and supplier collaboration, enabling organisations to manage complex, responsible, highly resilient and efficient supplier bases. Backed by 30 years of expertise, the company's AI-powered, industry-specific solutions, services and partnerships form JAGGAER One – serving directly and indirectly, upstream and downstream in settings demanding a comprehensive solution.

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Jacob Tyson

Following completion of an MSc degree in Medical Genetics from the University of Sheffield's (UK) Molecular Biology and Biotechnology department (MBB), Jacob Tyson is now working full time as a Senior Medical Writer for IMed Consultancy Ltd. Mr Tyson has a passion for scientific writing, especially in medicine and disease. He has authored 60+ clinical evaluations for a wide range of medical devices (including class IIIs and drug-device combinations) under the scope of the EU MDR, the EU MDD and the UK MDR 2002. Mr Tyson has also authored numerous performance evaluations for IVDs under the scope of the IVDR.

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Jon Lawrence

As Chief Product Officer at JAGGAER, Jon Lawrence oversees the entire product portfolio, ensuring that the product offerings continue to solve today's critical market challenges while addressing the future of procurement. Before joining JAGGAER, Mr Lawrence was tasked with leading innovation and the overall product strategy at CBORD, where he contributed to developing a strong product based on accurate and insightful market fit, in order to deliver high-value returns to clients and customers. Prior to CBORD, Mr Lawrence, who holds a Bachelor of Science degree from Cornell University (NY, US), covered senior product leadership roles in spend monitoring, supply chain management and retail operations.

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Interview
From Pilot to Scale Manufacturing

In this second exclusive interview with ONdrugDelivery, **Glenn Svedberg** of **Nolato** talks with Guy Furness about Nolato's role as a strategic partner for design, development and industrialisation within the pharmaceutical sector. In an engaging conversation, Mr Svedberg covers a wide range of subjects about Nolato, including the company's virtual factory, decentralised structure, approach to scaling up from single-cavity moulds to commercial production, regulatory expertise and global footprint, discussing how the company can use each of these elements to support its partners' device development and industrialisation programmes.

Q To begin with, could you give us a quick overview of Nolato and your position in the company?

A Nolato is an international public company headquartered in Sweden; it was founded back in 1938 and we've been listed on NASDAQ for 40 years. The company's revenue is around €1 billion (£850 million) a year and we have around 30 sites in 10 countries globally, roughly 20 of which have a medical certification.

Last year 56% of our revenue related to the life science and medical industries. The rest is what we call "Engineered Solutions", which cover a number of different identified product segments and market areas. In the medical sector, we split the business into four areas – pharmaceutical packaging, drug delivery systems, medical devices and diagnostics.

Not every one of our sites covers everything and we're not locked to one particular therapy area. We work with our customers' products to help them and carry them through from concept to high-volume production. We don't have our own product platforms – I know that some of our peers have developed their own pumps and autoinjectors, but that's not something we've done. We want to stay flexible, both in terms of technology and scale, and not compete with our customers.

As for me, I've been with the company for 18 years. I'm part of Nolato's executive group management and responsible both

Glenn Svedberg

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Glenn Svedberg has spent 30 years in the manufacturing industry in managerial, mainly commercial, roles. He started at Volvo Group in 1990 as a trainee in Purchasing, moving to Ericsson as a marketing manager for a production unit in 1994. In 1999, he joined Flex Northern Europe, assuming a role as Business Development Director and part of the acquisition team, as well as being Key Account Manager for ABB, globally. At Flex, he held different roles before becoming Managing Director for the company's Scandinavian operations, being responsible for 1,400 people across five factories. In 2005, he moved over to the plastic packaging industry and joined Rexam (today part of Berry Global) as a Managing Director for the company's sites in Sweden and Denmark.

Since 2007, Mr Svedberg has been part of Nolato and served as Managing Director for Nolato Cerbo, as well as Head of Pharma Packaging, and was located in the UK for two years when integrating Nolato Jaycare in 2012–2014. He is dedicated to lean principles as well as quality, and, in parallel to his MD role, he led the Medical Excellence programme across all Medical Solutions sites, globally, from 2017 to 2021. He has a genuine interest in sustainable development and has been laying the foundation for the work leading up to a Ecovadis gold status recognition for Nolato. In June 2021, he assumed his role as Group Sustainability Director at Nolato Group and Vice-President Business Development for Medical Solutions. Since 2023, he has also headed Nolato's Technical Design Centers in three regions – Europe, North America and Asia.

"OUR CORE STRENGTH IS DFM SERVICES, WHERE WE CAN BRING IN OUR EXTENSIVE EXPERIENCE AND APPLY MODERN TOOLS, SUCH AS VIRTUAL PROTOTYPING, WHICH LETS US ACHIEVE A LOT UPFRONT BEFORE WE START CUTTING STEEL."

for co-ordinating our business development operations within medical solutions and for our technical design centres (TDCs) globally. As we discussed at greater length in our first interview last year,[1] my role also includes a sustainability component, which may seem odd at first, but that whole triangle – sustainability, business development and technical – is something you want someone at the centre of because you can't do much with sustainability unless you have technical and business people involved in making it happen.

Q How does Nolato support its partners from the early design stages through to high-volume manufacturing?

A We offer an integrated approach that spans all the way from the earliest concept and the design stages through to industrialisation and validated-scale manufacture. This full-spectrum capability ensures a smooth and efficient transition from pilot to high-volume production. We bridge the gap between innovative device design and scalable, compliant manufacturing – helping customers to increase safety, accelerate timelines and bring better solutions to market faster.

Our core strength is design for manufacturing (DfM) services, where we can bring in our extensive experience and apply modern tools, such as virtual prototyping, which lets us achieve a lot upfront before we start cutting steel. When we get an initial design, we can use virtual prototyping software to get a really good look under the hood and help our customers identify pain points in the design before they occur in physical prototyping. For example, we can investigate how locks or hatches are working and use these virtual tools to demonstrate that for the customer before we start to apply a tool strategy, which is very helpful because it enables us to have more robust and productive discussions (Box 1).

At the same time, we make sure to include eco-design principles – by using simpler materials and lower weights, we can make a component that has a lower carbon footprint and is more cost competitive. We also sometimes employ rapid prototyping if needed, but we often only do that as a final iteration step when we've had the earlier discussions. And, for a drug delivery device, it's also critical to involve the quality assurance section.

We ensure that there is a full audit trail from day one that we can supply to our customers for their design history file. Of course, each customer will have their own process so, while we have a general process for product development projects, we are able to adapt it to the needs of the customers. If we have a site that has experience in a certain therapy area or a certain type of device, we do our best to involve them as early as possible to facilitate clear and productive discussions.

BOX 1: NOLATO'S VIRTUAL FACTORY

By using digital tools and combining modelling software approaches, medical device design can be made more robust and reliable before ever making a physical prototype (Figure 1).[2] Nolato combines mould flow simulations with measuring software, such as computed tomography (CT) scanning, to model devices and identify design hotspots early, and to iterate on the device throughout development. Taking this approach can help to avoid:

- Project delays
- Tool adjustments
- Moulding imperfections
- Material changes
- Manufacturing defects affecting device functionality
- Delayed process qualifications
- Unpredictable outcomes
- Late and costly design changes
- Inaccurate measurements
- Expensive moulds.

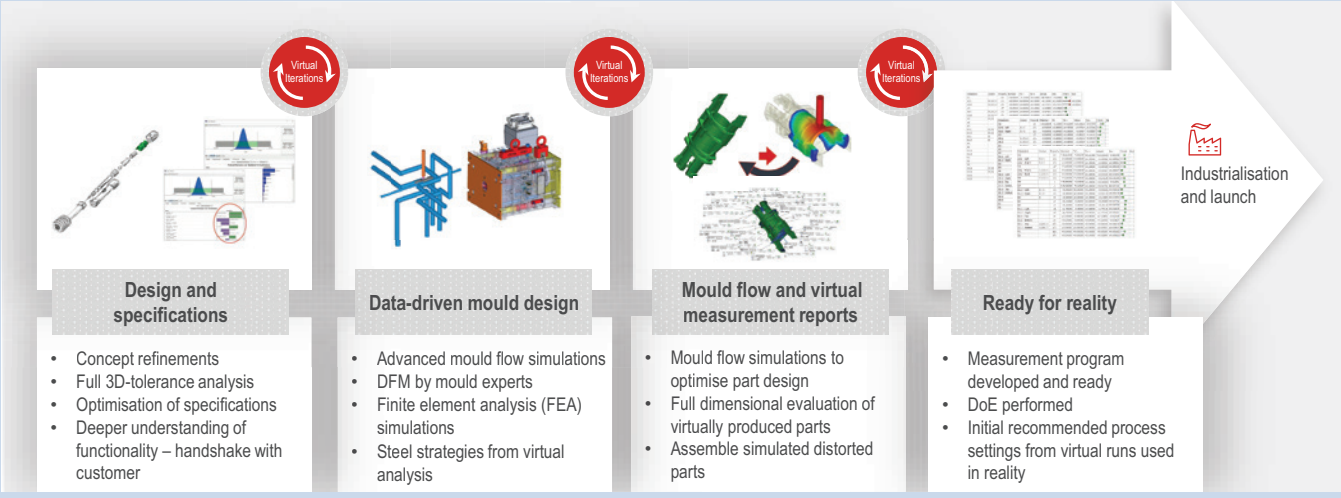

Figure 1: Nolato's virtual factory process.

Similarly, we try to include any site that's going to be involved in the development or industrialisation process as early as possible, for example if a US-based company wants our help establishing manufacturing in Europe. We are a decentralised company, so don't have a lot of centralised engineers. Our TDCs are able to support a given project, but the majority of the work is done by the individual companies that make up Nolato Group. That's why we see it as pivotal that they have a stake in the project, so they are involved from the beginning.

As an example, just this week I was involved in a project we started some years ago with a Boston (MA, US)-based company. The project was for a device in the insulin field that we worked on some components for at a quite early stage – they wanted to have manufacturing in Asia, so we made some parts in Asia for them. They then came up with a much more complicated technology and they had a Swiss tool maker for the advanced manufacturing process it required, and we happened to have experience with that tool maker for a similar product; it had a completely different application but still used the same basic technology.

So we brought them together and now we will start to scale that up and validate it because it will be quite a long project, maybe a year and a half. Then, when everything is set up and approved, we can transfer the tool to the Asian site.

Typically, we prefer to put processes in place at the target site from day one, but in this case we wanted to work with the tool maker in a closer and more controlled way. That's how we use our small pieces of the puzzle and combine them in a clever way.

Q How does Nolato ensure that taking the step from design verification to industrialisation is robust and risk-free?

A We understand that the transition from design verification into industrial production is one of the most critical phases. Nolato uses a phase-gated process that integrates design validation, risk analysis and process development. Our cross-functional teams – spanning R&D, engineering, quality assurance and production – work together to transfer designs into robust manufacturing processes. We develop scalable tooling, automation concepts and validation protocols in parallel, ensuring a seamless shift into commercial production without compromising quality or compliance.

An important aspect to discuss is user requirements. Customers can have a very subjective view of their requirements, so for us it's about getting a feel for expectations, seeing where we can and can't push, and then converting that into concrete product requirements. That's the TDC core competence; we can help with establishing requirements at an early stage (Figure 2). Once that's settled, we get into the core competence of Nolato, which is the single concept selection. If there are several ideas, we can do simulations and highlight the potential risks and different challenges with various solutions, giving customers what they need to make an informed decision about how to proceed.

Q What capabilities does Nolato offer to accommodate different production volumes, from clinical to commercial?

A Our infrastructure is designed for flexibility. We support pilot-scale production with semi-automated or manual processes, ideal for clinical and early commercial phases. As demand grows, we scale seamlessly to fully automated, high-volume manufacturing – often in cleanroom environments depending on the requirements. We also design and implement customised manufacturing cells and automation systems tailored to each customer's device and lifecycle stage. This scalability is a key reason why leading pharma companies choose Nolato as a long-term partner.

Sometimes this transition involves different parts of the customer's organisation, which can present a challenge. For example, imagine a project-aligned team focused on the early development stages handing over to a production team

"OUR CROSS-FUNCTIONAL TEAMS – SPANNING R&D, ENGINEERING, QUALITY ASSURANCE AND PRODUCTION – WORK TOGETHER TO TRANSFER DESIGNS INTO ROBUST MANUFACTURING PROCESSES."

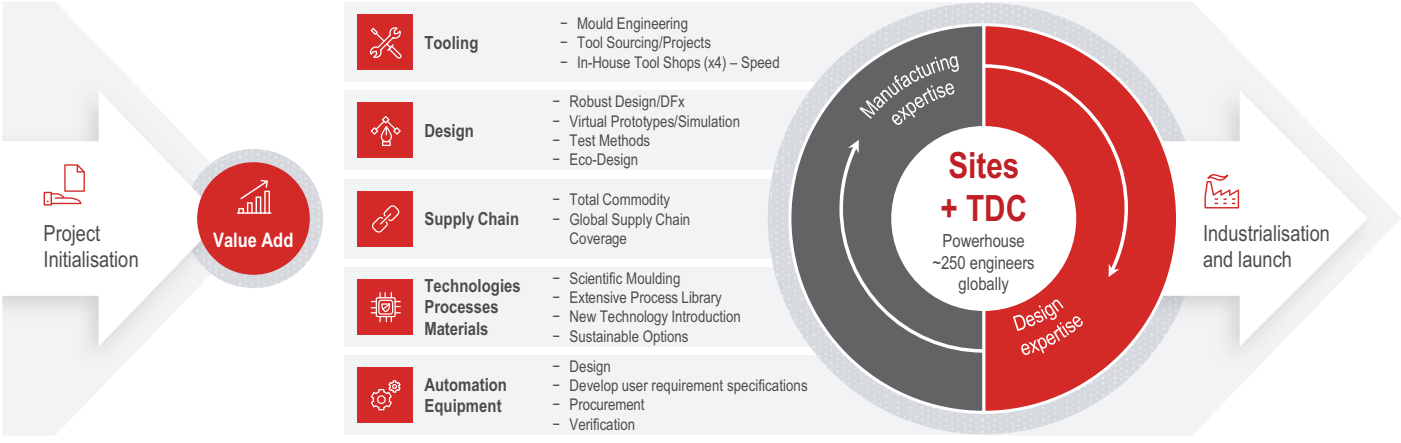

Figure 2: Capabilities of Nolato's TDCs.

Figure 3: Nolato can provide localised manufacturing for a target market with a global approach that ensures quality and consistency.

– because we work with both small and large scale, Nolato can help by carrying information and knowledge between those teams, providing continuity for the project. Other times we'll be helping communication and transition between different locations.

Another aspect that's easy to overlook is making sure that scale-up and DfM are considered at every stage, which is core to Nolato's approach. It can be easy to get lost focusing solely on performance and meeting critical dimensions and tolerances, which can lead to a good and robust device but one that's difficult and expensive to scale up. You need to think about scaling up from the beginning and continue to keep in mind as you move from single- to multi-cavity tools, all the way up to full commercial scale. Ideally, we always try to do this all within the same factory, using the target site from the very first day through the long term, even if that means a lower quantity to start with.

Q Could you go into some more detail about how Nolato helps to ensure that manufacturing processes are regulatory ready?

A We have a global quality network that is headed by one of the senior quality directors, but, due to our decentralised structure, there is no one single quality system for Nolato – the individual companies have their own quality management systems (QMS) and select what certifications they need given their business profile and customer base, tailoring their approach to best suit their needs. As such, we try to keep overall corporate guidelines as limited as possible.

Having said that, we do have a standard framework in the medical sector that we call the "Medical Excellence Model", wherein regulatory compliance is baked into our process from the start. Whether it's for ISO 13485, US FDA or EU MDR compliance, or even customer-specific requirements, our teams are well-versed in designing and validating processes that meet global standards. We develop detailed validation plans and ensure traceability and data integrity throughout. Our customers can rely on us not just for technical expertise, but for regulatory peace of mind as they approach market launch.

"CENTRAL TO THIS IS THAT WE VIEW OURSELVES AS AN EXTENSION OF OUR CUSTOMERS' TEAMS AND INVEST IN LONG-TERM PARTNERSHIPS, NOT JUST SHORT-TERM CONTRACTS."

We can also use the expertise of certain sites that have experience handling specific interactions with the FDA, for example. There's a whole language involved with dealing with regulators, so we try to maximise value for our customers by identifying which companies within Nolato have the most experience with the relevant regulatory bodies. For example, we had an FDA audit at one of our Swedish sites handling advanced device modules just two weeks ago. It all went very well and that company used their local QMS, supported by a few of our global guidelines, and there were no issues. Ultimately, it comes down to providing the customer with the best possible support.

Q What makes Nolato a valuable strategic partner rather than just a supplier?

A Central to this is that we view ourselves as an extension of our customers' teams and invest in long-term partnerships, not just short-term contracts.

"OUR COMPANY CULTURE OPERATES ON THREE CORNERSTONES – BE PROFESSIONAL, BE ORGANISED AND TAKE RESPONSIBILITY."

Our involvement goes beyond the factory floor – we collaborate on technical strategy, supply chain planning and risk mitigation. Our global footprint really helps us here, as it enables us to cover for gaps in our customers' capabilities. For example, a customer might have a strong presence in the US and Asia, but not so much in Europe, but we have a footprint in all three of those major regions so can provide the European coverage (Figure 3).

Another factor is that we are quite flexible in terms of approving new investments. For example, we had an opportunity in Malaysia, where we have a site manufacturing for Engineered Solutions customers. A lot of our customers these days want to have options in South East Asia for accessing China. We started with a small cleanroom in our existing facility in Southeast Asia with the aim of going to market from there. Then, while that was in progress, we also won some other business in the region and are now considering expanding with a larger site. All within one quarter, we identified a new building and put together the business case, which is likely to go ahead, giving customers real confidence.

Then there's our decentralised structure, which supports that agility and enables us to take decisions much closer to customers and makes our approach unique. This is possible because our company culture operates on three cornerstones – be professional, be organised and take responsibility. This is something that we truly believe in and is part of the Nolato spirit.

Cross-fertilisation between the different product areas within the larger Group is also key to our success. Because ideas flow freely within the company, we can get a clear view of trends across the sectors we operate in, such as miniaturisation, connected devices and increased inclusion of electronics. We can then pull that knowledge from fast-moving sectors, such as consumer goods and mobile phones, and implement what we've learned in the medical arena.

As a strategic partner, we can pool all of these advantages and really deliver for our customers. In practice, we've found that this strategic alignment is critical for successful device launches for our pharma and biotech partners, and we will continue that journey with them.

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2025/26 Editorial Calendar

Each issue of ONdrugDelivery focuses 100% on one specific topic *within* drug delivery.

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OCT/NOV Sustainability in Drug Delivery DEADLINE: **Sep 18, 2025**	**NOV** Pulmonary & Nasal Drug Delivery DEADLINE: **Oct 2, 2025**	**DEC** **NEW ISSUE TOPIC** Delivering Gene & Cell Therapeutics DEADLINE: **Nov 6, 2025**
JAN 2026 Prefilled Syringes & Injection Devices DEADLINE: **Dec 4, 2025**	**FEB** Skin Drug Delivery: Dermal, Transdermal & Microneedles DEADLINE: **Jan 8, 2026**	**MAR** Ophthalmic Drug Delivery DEADLINE: **Feb 5, 2026**
APR Pulmonary & Nasal Drug Delivery DEADLINE: **Mar 5, 2026**	**APR/MAY** Sustainability in Drug Delivery DEADLINE: **Mar 19, 2026**	**MAY** Delivering Injectables: Devices & Formulations DEADLINE: **Apr 2, 2026**
MAY/JUN Oral Drug Delivery DEADLINE: **Apr 16, 2026**	**JUN** Connectivity in Drug Delivery DEADLINE: **May 7, 2026**	**JUL** Industrialising Drug Delivery DEADLINE: **May 21, 2026**

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