



A LARGE-VOLUME AND HIGH-VISCOSITY AUTOINJECTOR DELIVERY PLATFORM FOR BIOTHERAPEUTICS

SMC[®] Ltd.

Asmita Khanolkar, Marta Vilaplana, Susanna White and Pete Evans, all of SMC Ltd, present the Bios platform, designed to simplify device development for the delivery of biologics while maintaining identical key design aspects across all Bios variants.

As today's medicines evolve to include biotherapeutics, the complex delivery needs for the self-administration of high-concentration, high-viscosity and large-volume doses continue to increase. Achieving the optimal concentration for therapeutic efficacy in a patient-preferred, self-administration setting requires new device solutions for subcutaneous (SC) rapid delivery. SMC's Bios autoinjector platform solution has capability for large-volume delivery (up to 5.5 mL) and high viscosity for rapid delivery (under 30 seconds).

RAPID SC DELIVERY

Although it has been established that SC delivery of larger volumes is feasible, this has mainly been established for

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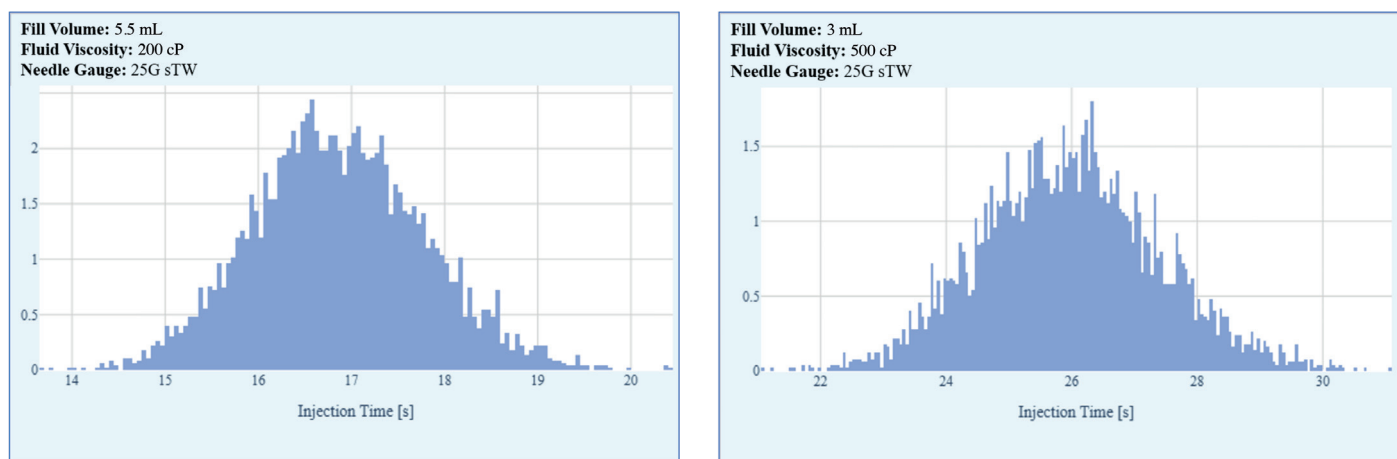


Figure 1: Delivery time evaluation with dose (fill volume), viscosities and needle sizes.

injections with longer injection times. Dose volumes of 3–5 mL in a rapid delivery setting via an autoinjector continue to remain an area of development, as there are several challenges to consider while developing an autoinjector solution for large-volume SC delivery.

Mechanical Design Limits

The power required to deliver large volumes via an autoinjector is substantially higher than for typical volumes (around 1 mL). Although high-energy springs can be used, they increase in size substantially and pose challenges for material creep limitations on components in the design. A more flexible energy source is necessary. Compressed gas as an energy source poses a better alternative to compression springs, as the energy density is sufficient to cover the design limits within a realistic size. Additionally, gas management (release and control of pressure) is predictable and consistent.

Injection forces and pressure must increase within the system to achieve rapid delivery. Most biologics use glass containers where vulnerability to fracture can limit capabilities. Staked-needle syringes offer more flexibility for ready-to-fill solutions and offer the potential to use both glass or polymeric options for syringes that can tolerate high pressure. However, in general, options are limited for high-pressure systems in currently available standard syringe containment closure system configurations.

Additionally, drug compatibility and silicone-free requirements may limit the selection even further. Luer Lock syringes

may not withstand the required pressures, although they can be suitable for low-pressure applications (e.g. 5 bar). Staked-needle options are now available for glass up to 5.5 mL, although polymeric options for staked-needle syringes are not currently commercially available for large-volume applications.

Dose and Tolerability

Several factors need to be considered regarding patient tolerability with rapid injections, such as pharmacokinetics, pain, discomfort, leakages and injection site reactions. Some considerations, such as concentration, viscosity, temperature, pH, homogeneity and flow properties, are drug-related factors to be optimised. On the device side, needle selection, injection time and depth play an important role for patient tolerability. Smaller needle gauges are associated with less pain, although the speed of injection and jetting effects may potentially affect pain levels. Delivery optimisation with the injection parameters can be considered and mapped ahead of use, even in the case of suspensions or non-Newtonian formulations where the flow behaviour may be influenced by environmental factors (Figure 1).¹

Usability

The size of the device needs to accommodate the large-dose container as well as the form factor suitable for self-administration. Autoinjectors that can provide ease of use for a large dose can improve patient adherence and device adoption. While size and form factors

“WHILE SIZE AND FORM FACTORS ARE AN IMPORTANT CONSIDERATION, WHEN DESIGNING FOR LARGE-VOLUME DELIVERY, THE PATIENT’S ABILITY TO HOLD THE AUTOINJECTOR IN PLACE FOR THE DURATION OF INJECTION IS ESSENTIAL, AS EARLY REMOVAL CAN RESULT IN WET INJECTIONS AND INCOMPLETE DOSING.”

are an important consideration, when designing for large-volume delivery, the patient’s ability to hold the autoinjector in place for the duration of injection is essential, as early removal can result in wet injections and incomplete dosing. Dexterity, vision and hearing considerations for the target population must also be considered while designing the viewing window, other audio and visual dose confirmations, and general grip and handling of the device.

Instructions for use and packaging require additional scrutiny for large-volume injections. In most cases, a change requiring larger-volume delivery stems from higher dose requirements, a transition from intravenous to SC delivery or a move from daily, weekly, monthly or quarterly injections (towards less frequent injections). In all these examples of large-volume SC delivery, the goal is to maintain the pharmacokinetic and pharmacodynamic profile for therapeutic efficacy while dose changes are implemented. In the case of refrigerated formulations sensitive to viscosity changes related to environmental conditions, the combination-product interactions (dose, syringe and device) must be understood as part of early feasibility studies. These help to inform the content of instructions for use and build real-use scenarios in subsequent formative studies. These are essential, as if the patient cannot use the device correctly, the dose is not delivered completely and the therapeutic effect is not achieved.

THE BIOS PLATFORM APPROACH

Delivery of biotherapeutics is challenging, as these formulations are typically delivered at high concentrations and/or high doses to achieve therapeutic effect. A balance must be struck between concentration/viscosity and volume as well as the delivery time for self-administration. Other factors to be considered for biotherapeutics are stability and shelf life. As sensitive formulations, they are prone to agglomeration and degradation. Container strength, shear forces through the needle, container compatibility and cleanliness are additional requirements for container selection. Flexibility of multiple syringe/rigid needle shield/stopper combinations and a high-energy power source are

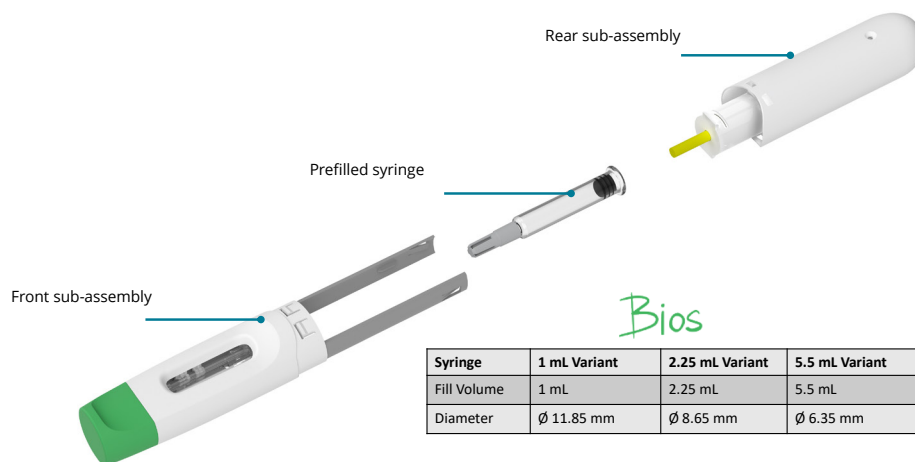


Figure 2: Bios platform configuration with 1 mL long, 2.25 & 5.5 mL ISO 11040-compliant variants.

Device Specifications	1 mL Variant	2.25 mL Variant	5.5 mL Variant
Primary Container	1 mL long	2.25 mL	5.5 mL
Delivered Volume	0.5–1 mL	1–2 mL	3–5 mL
Viscosity	Up to 1,000 cP	Up to 1,000 cP	Up to 500 cP
Staked-needle diameter	25–29G	25–29G	25–27G
Injection time target	Under 10 s, dependent on patient tolerability	Under 15 s, dependent on patient tolerability	Under 30 s, dependent on patient tolerability
Prefilled syringe shield	Rigid	Rigid	Rigid
Target needle insertion depth	~6 mm	~6 mm	~6 mm
Injection feedback	Audible and Visual	Audible and Visual	Audible and Visual

Table 1: Bios platform device specifications.

requisites for a solution to accommodate the challenging delivery requirements.

Given the challenges of large-volume delivery, a platform approach is ideal for the multiple volume, viscosity and needle requirements to consider for targeted therapies and precision medicines designed to be self-administered or delivered in a home

setting. Bios is a flexible platform solution, which includes a gas-powered powerpack and accommodation of ISO 11040 staked-needle options.² It also accommodates the geometries of commercially available 1 mL long, 2.25 and 5.5 mL staked-needle syringes without a major change in form factor (Figure 2 & Table 1). The mechanisms defining device function and performance, as well as critical part features are the same across all Bios variants. Platform benefits include a patient-centric design, flexible and simple reconfiguration, sterilisation path options and appropriate drug contact materials. Key features include a simple two-step, one-handed operation, audible, visual and tactile feedback, along with a permanently hidden needle and passive needle safety aspects.

“GIVEN THE CHALLENGES OF LARGE-VOLUME DELIVERY, A PLATFORM APPROACH IS IDEAL FOR THE MULTIPLE VOLUME, VISCOSITY AND NEEDLE REQUIREMENTS TO CONSIDER FOR TARGETED THERAPIES AND PRECISION MEDICINES DESIGNED TO BE SELF-ADMINISTERED OR DELIVERED IN A HOME SETTING.”

The rear sub-assembly, which contains the powerpack and the activation mechanisms (including the pressure chamber and gas canister), is kept the same across all Bios configurations. The front sub-assembly holds the syringe and has change components that can hold all three different syringe sizes. Configurable prefilled syringe options with ISO 11040-compatible containers address the high-pressure requirements. A powerful gas-powered powerpack addresses delivery in acceptable injection times.

Human Factors Research

Human factors research is an integral part of development when considering a truly patient-centric approach for self-administration. Understanding and implementing patient preferences helps to ensure smooth usability of platform devices.

A 20-participant study of adults with two patient groups was completed. The first group was a mix of potential users that included both autoinjector-aware and naïve users; the second group consisted of users with manual dexterity issues. Patients with chronic diseases such as rheumatoid arthritis, Crohn's disease, multiple sclerosis and metabolic and autoimmune diseases were also included in the study. The study was successfully completed by all participants with no use errors.

Some of the human factors considerations for the Bios platform included low force to hold the device in place during injection – an especially relevant consideration for large-volume injections – device size, grip, presentation and visual and audible confirmation of injection.

Delivery Modelling

Multiple empirical studies across various larger-dose volumes and viscosities have been conducted to gather data for the Bios platform delivery model. Testing using viscosity mimics and a range of fill volumes from 0.5 to 5 mL were used to develop the model. Functional device testing was also conducted to assess cap removal, activation force, extended needle depth, dose accuracy, injection time, delivered dose and needle safety as part of the platform development. The design testing envelope covered fill

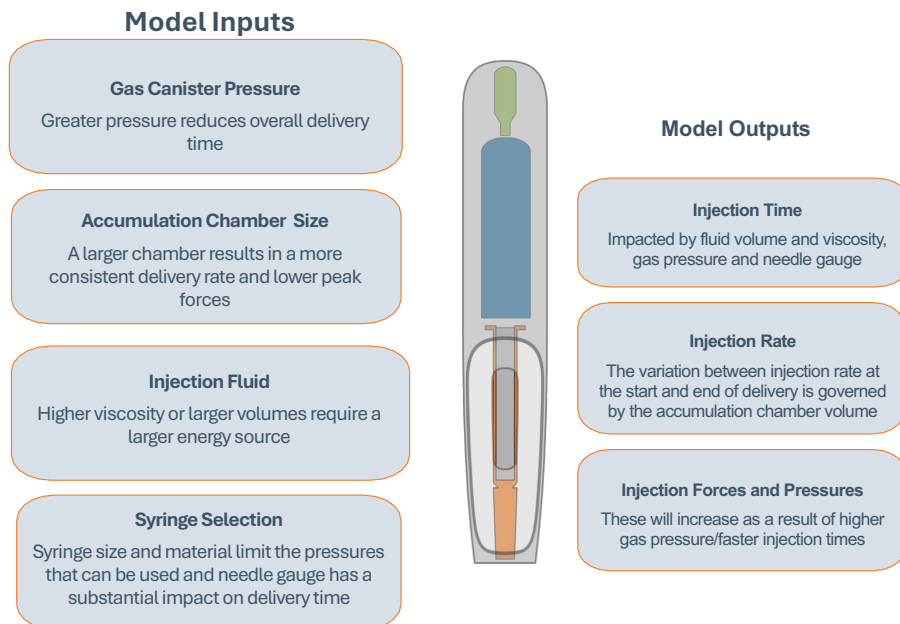


Figure 3: Model development for the Bios platform configuration.³

volumes from 0.5 to 5 mL over a range of viscosity mimics and a range of gas pressures from 60 to 205 bar.

Based on empirical data, using the ideal gas law and the Hagen-Poiseuille equation framework, a mathematical model has been created for use of the

Bios platform (Figure 3). Outcomes can be derived based on different input scenarios to predict injection time, delivery consistency, forces and pressures. This validated model is the foundation for understanding specific configurations of the platform design envelope – it improves

“OUTCOMES CAN BE DERIVED BASED ON DIFFERENT INPUT SCENARIOS TO PREDICT INJECTION TIME, DELIVERY CONSISTENCY, FORCES AND PRESSURES.”

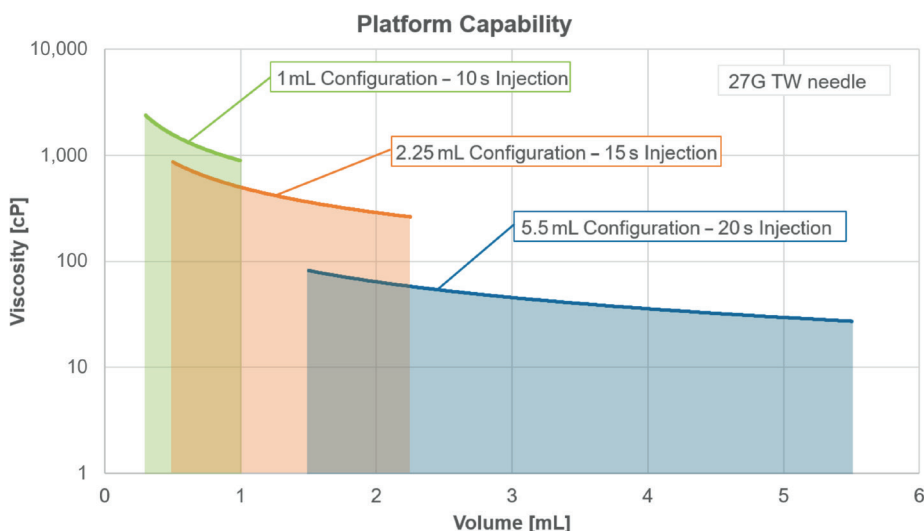


Figure 4: Bios platform delivery capability for a 27G thin-wall needle and specific target delivery times.

the accuracy of predicted results without costly and time-consuming testing of multiple variables.

Platform Capability

The Bios platform capability covers a large range of doses and viscosities for various formulations (Figure 4). Based on the combination of product requirements, the energy source, syringe selection and syringe needle combinations can be configured to achieve optimal delivery. The device can also be manufactured to configurations for clinical and commercial volume launches.

CONCLUSION

The Bios autoinjector platform is capable of delivery of large-volume (up to 5.5 mL), high-concentration formulations, helping to provide additional options for the self-administered delivery of complex formulations to the patients that need them. The platform offers configurability

of energy source, container and needle selection, thus providing freedom to optimise challenging therapeutic formulations and their delivery.

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"THE BIOS AUTOINJECTOR PLATFORM IS CAPABLE OF DELIVERY OF LARGE-VOLUME (UP TO 5.5 mL), HIGH-CONCENTRATION FORMULATIONS, HELPING TO PROVIDE ADDITIONAL OPTIONS FOR SELF-ADMINISTERED DELIVERY OF COMPLEX FORMULATIONS TO THE PATIENTS THAT NEED THEM."

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Asmita Khanolkar

Asmita Khanolkar, Senior Director at SMC Ltd has a Master's degree in Materials Science & Engineering from Worcester Polytechnic Institute in Worcester, MA, US. With over two decades of manufacturing experience specialising in the medical device and pharmaceutical industry, she has managed various device projects from concept to commercial launch. Her product portfolio includes single-use, wearable and implantable devices, drug-device, device-biologic combination products for drug delivery, biotherapeutics and pharmaceutical applications. She has held various engineering and management roles in new product development, manufacturing engineering, advanced quality planning, operations, supply chain and product life cycle management. Her current responsibilities include a corporate leadership role supporting multiple sites in early technical engagement through commercialisation for medical devices, combination products and pharmaceutical services.

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Marta Vilaplana

Marta Vilaplana is a Manager of Device Development at SMC Ltd with over 15 years of technical experience in the medical device and pharmaceutical industries. She has specialised in the design and development of combination products, leading programmes from early-stage concepts through to clinical readiness. Her expertise includes the engineering of precision mechanical systems, device-drug compatibility and the integration of product and industrial design into robust delivery platforms. Ms Vilaplana has contributed to the development of a broad range of injectable and inhalation systems, with a strong focus on reliability, manufacturability and regulatory compliance. Her current responsibilities include leading combination product programmes that translate complex technical requirements into practical, patient-ready solutions. She continues to focus on advancing delivery system technologies that enhance usability, improve therapeutic outcomes and meet the evolving needs of patients and healthcare providers. Ms Vilaplana graduated from the University of Barcelona (Spain) with a BEng(Hons) in Industrial & Product Design Engineering.

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Susanna White

Susanna White is a Senior Device Development Engineer at SMC Pharma Services, with over a decade of experience in the design and test programmes for SMC's innovative autoinjector technology platforms. Much of her work has focused on the study of highly viscous and non-Newtonian drug formulations – using numerical modelling techniques in combination with experimental investigation in order to achieve the most appropriate delivery system for challenging formulations. Ms White graduated from the University of Cambridge (UK) with a Master's degree in Engineering for the Life Sciences.

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Pete Evans

Pete Evans, Director of Device Development at SMC Ltd, has been involved in the development of novel drug delivery devices for more than 25 years, working on inhalers and both pen and autoinjectors. With a career in both consultancy and industry, he has worked across all phases of development – from conception to commercialisation – for both device platforms as well as combination product developments. Mr Evans' current role is based at the SMC Ltd site in Cambridge, UK, developing innovative injection devices with the capabilities to inject the challenging drug formulations that are increasingly prevalent, due to the growth in biologics and long-acting treatments.

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