

SHL GROUP

THE MAKINGS OF INNOVATION IN ADVANCED DRUG DELIVERY

In the context of recent industry trends and market demands, including the emergence of biosimilars and increasingly viscous formulations, SHL provides an update on its portfolio of auto-injector products, including two new devices, Maggie® and Bertha™.

Since almost 30 years ago, when the first commercial auto-injector was created for emergency use, the advanced drug delivery market has continued to grow. In fact, self-administered auto injection and pen injection using prefilled syringes or cartridges has become one of the fastest emerging drug delivery solutions of recent years, with one study forecasting that the market will grow at an annual rate of 7.6% until 2026.¹

The purpose of developing any medicine is to improve the lives of patients, and how the medicine is delivered needs to support this original intent. Initially created for emergency use, the auto-injector was designed to be operated by patients or untrained users. While its range of users has expanded, the auto-injector, by nature, has remained intuitive and easy to use so as to support patient convenience and compliance.

DESIGNS THAT BOOST CONFIDENCE

With nearly three decades of experience designing and developing auto-injection devices for 80% of the world's top 25 pharmaceutical companies, SHL has always been focused on every detail when creating solutions to help its partners benefit the patient. SHL's in-house design team constantly looks into ways to improve devices for better usability. The team works

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independently or in collaboration with our pharmaceutical partners to conduct human factors (HF) studies that help us gain insight about how the patient uses, understands and accepts the device.

The evolution of the steps required to use our injection devices exemplifies the improvements we have made throughout the years based on user research. While our easy-to-use, three-step auto-injector revolutionised the market standard for injection devices, a significant finding from our HF studies was that buttonless auto-injectors were preferred among a majority of patient groups. Our devices were therefore simplified to include just two steps – uncap and inject – to make the injection process easier and more intuitive. By removing the activation button and simplifying the injection process, we were also able to reduce the risk of handling errors. This gave patients an added sense of autonomy during self-administration, helping them feel more confident about self-injection.

Providing the patients with a clearer view into the self-administration process is also

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Figure 1: The Molly® family of devices (from left to right): Molly 1.0 mL FNS, Molly 1.0 mL RNS and Molly 2.25 mL.

crucial for improving patient adherence and compliance. A way to enhance patient insight is through a clear feedback mechanism, which can be achieved via a combination of audible, tactile and visual indicators, to reduce the uncertainty related to injection.

Our two-step Molly® auto-injector, for example, features two distinctive audible clicks – one at the beginning and one at the end of injection – to indicate clearly when the injection starts and ends.

The Molly® family of devices (Figure 1), which come in 1.0 mL rigid needle shield (RNS) and flexible needle shield (FNS) formats as well as a higher 2.25 mL fill volume, are also designed with large viewing windows to enable real-time visual monitoring of the drug's delivery.

To further enhance confidence and understanding, a range of SHL devices are now designed with a continuous clicking mechanism to provide constant feedback throughout the entire injection process. Other details, such as tactile feedback on the needle guard, also add to the patient's confidence when using the device.

SUPPORT FOR HIGHER VOLUMES & VISCOSITIES

An important factor contributing to growth in self-administered injection devices is the increased prevalence of chronic diseases, and in turn the rise of biological and biosimilar drugs to treat these indications. In fact, the biopharmaceutical market accounts for about 20% of the pharmaceutical market as a whole and, due to their effectiveness in treating chronic conditions, biologics and biosimilars are expected to grow at an annual rate of over 8% per year.²

Chronic disease management is a lifelong process, meaning that many treatments are moving from hospitals to the home. Pharmaceutical companies are also developing biologic therapies that require less frequent injections so as to increase patient comfort and convenience, and also to differentiate themselves in the market.

As large molecules, biologics need to be given in high concentrations in order to achieve efficacy and prolong the duration between treatments. This can either result in formulations that are highly viscous and/or have larger volumes. Existing auto-injection devices are therefore being challenged to deliver these new forms of biological formulations effectively, without compromising patient comfort.

This challenge led to the development of Bertha™, a disposable auto-injector created for the delivery of drugs in larger volumes and of higher viscosities. Bertha™ uses SHL's intuitive two-step operation and is compatible with either a 1.0 mL or 2.25 mL prefilled syringe. At the same time, it features the continuous clicking mechanism for enhanced feedback. Its larger design also provides the user with an extra sense of reliability during the injection process.

Meanwhile, SHL's market-proven Rotaject® technology supports biological formulations of even higher viscosities. The Rotaject® uses a clock spring technology, enabling the delivery of a viscous drug at a constant force (Figure 2). This helps ensure that the full dose is safely delivered. The steady and safe delivery also allows us to optimise the patient's injection experience. To meet the request for a wider variety of fill volumes, the technology can be customised into a disposable auto-injector design using either a 1.0 mL or a larger 2.25 mL syringe.

A HIGHER BAR FOR SAFETY

Also supporting the trend for auto-injection systems are a number of advantages associated with using a prefilled syringe or cartridge as a primary container, such as convenience, accuracy, sterility and safety. Once filled with a medication, prefilled syringes can remain sterile for two to three years.³ This not only helps pharmaceutical companies minimise drug waste, but also allows drug producers to create market differentiation. Meanwhile, the fact that patients do not

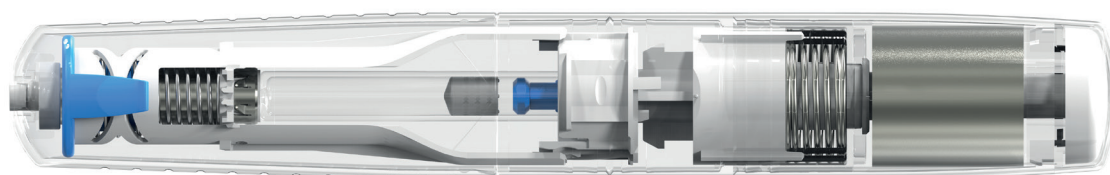


Figure 2: The Rotaject® technology uses a constant force technology that allows the delivery of highly viscous formulations of up to several hundred centipoise.



Figure 3: The cartridge-based Maggie® two-step auto-injector is equipped with SHL's unique Needle Isolation Technology.

need to transfer the drug from a vial to a syringe ensures the delivery of a precise dose.

Auto-injectors using prefilled syringes are designed with pre-attached needles, but those using cartridge-based solutions are not. As a result, cartridge-based solutions pose a challenge in terms of avoiding contamination and preventing needlestick injuries. To address this challenge, SHL developed the Needle Isolation Technology (NIT®), a unique solution where the needle is pre-installed in the device. Using a simple and risk free step, the user initiates the automatic needle attachment process without being exposed to the needle. With this technology, we ensure that the needle is permanently hidden throughout the entire process.

As cartridges offer a broad range of options for fulfilling various drug characteristics and therapeutic needs, this technology widens the scope of container choices, including for both single- and dual-chamber therapy solutions. With a maximum fill volume of up to 3.0 mL, cartridges can also support drugs in higher volumes.

SHL's new Maggie® (Figure 3), for example, uses a 3.0 mL standard ISO cartridge with NIT® to prevent metal leachables from contaminating the drug product. Maggie® has also been designed with a constant clicking feedback. These features were designed to help increase the patient's acceptance of the device and ensure patient safety throughout the injection process.

EFFICIENT MANUFACTURING

Development of a new therapy is a complex process that requires careful planning and meticulous execution. With growing competition in the market of biologicals and biosimilars, speed-to-market is as important as the technical specifications of the device. Therefore when it comes to choosing a device partner, the capacity, scalability and efficiency of

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their manufacturing capabilities are vital indicators of the ultimate success of a product's launch.

As a world-leading solution provider of advanced drug delivery systems, SHL has significant leverage when it comes to the manufacturing of device. The company keeps key capabilities in-house to ensure that each component of a device is considered at the outset of the design phase as well as throughout the entire development process.

Moreover, developing and manufacturing devices, as well as much of machinery that produces them, in-house allows us to customise existing offers in our pipeline. This process also makes it possible for us to develop completely bespoke devices based on the unique requirements of our customers.

The Molly® family of auto-injectors, for example, is part of a preconfigured programme that supports shorter production timelines and faster time-to-market. First made available in a rigid needle shield (RNS) format, Molly® was developed with a range of spring options that can be adapted to suit a variety of drug characteristics. Its intuitive features and compact design also make the device more appealing and less frightening for the patient. But perhaps most importantly, Molly® was designed with a unique power pack that offers the same functionality while using a significantly reduced number of components. For pharmaceutical

companies, this means that the timeline and investment required to develop a Molly® auto-injector can be significantly reduced. At the same time, Molly® still offers customisation flexibility that meets the requirements of various drug specifications and branding.

A COMPLETELY INTEGRATED SOLUTION

To ensure a smooth market launch, SHL also offers robust final assembly, packaging and labelling services for SHL-designed drug delivery devices. These services create added value for our partners following the successful design and development of their device. This total integration between device and assembly machine development guarantees faster communications and tighter quality control, resulting in a fully integrated service from device design to commercialisation.

Combining our core speciality in designing patient-centric auto-injection devices with our broad range of in-house expertise and services, SHL continues to lead the market with innovative drug delivery solutions for the pharmaceutical and biopharmaceutical industries. Designed with incredible attention to detail, SHL's innovative auto-injection systems make it easier and safer than ever for patients to self-administer therapies at home, improving their treatment outcomes and their lives.

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