WEARABLE INJECTORS

ON drugDELIVERY

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WEARABLE INJECTORS

This edition is one in the ONdrugDelivery series of publications from Frederick Furness Publishing. 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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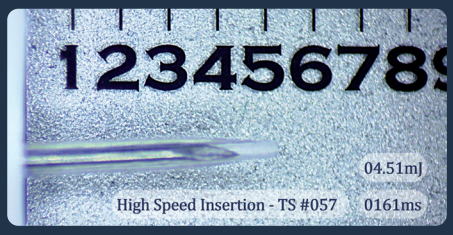

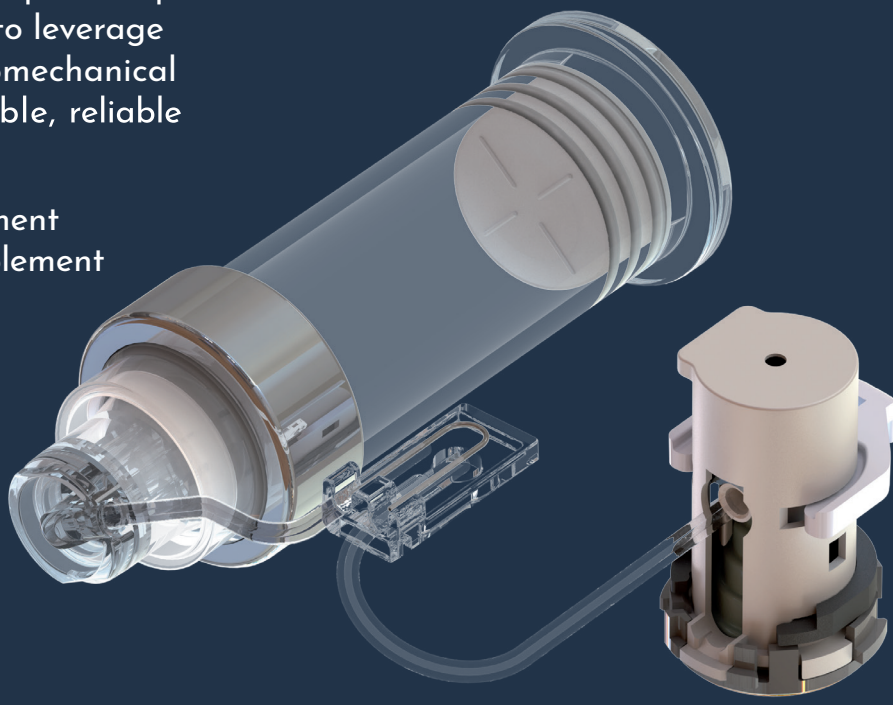

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WEARABLE INJECTORS: LATEST DEVICES & RECENT TRENDS

Tom Oakley, Director of Drug Delivery Device Development at Springboard, discusses recent trends in wearable injection devices. He also takes a look at devices currently on the market and considers the future of wearable injectors.

There are big changes underway in the market for wearable injection devices. In this article, we shall examine:

- The changing needs and competition
- Strategies for designing a wearable injector
- The current state of wearable injectors
- Progress on international standards
- A look to the future of wearable injectors.

THE NEEDS AND COMPETITION HAVE CHANGED

Wearable injection devices have been around in one form or another for decades, ranging from relatively small devices such as insulin infusion pumps to large injectors like the Freedom60 (Figure 1) from KORU Medical Systems (Chester, NY, US). Now there are many small wearable injection devices in development for drugs other than insulin, and some have reached the market.

The need for new wearable injectors has been driven by several factors, for example:

- Many new high-value drugs are biologics, and some biologics have either a viscosity or a volume (or both) that are too high for other delivery devices such as autoinjectors.
- Some new drugs require specific dose timing, for example the start time, or flow rate.

Wearable injectors (sometimes also called patch pumps, on-body delivery systems, or bolus injectors) were predicted to be widespread in many indications, but that has not happened yet. Why not?

Pharmaceutical companies tend prefer to deliver drugs orally if possible, because the oral route has high patient acceptance and relatively low costs. If a drug must be injected, then pharmaceutical companies tend to look at packaging in vials and prefilled syringes, and then autoinjectors or pen injectors for increased usability. Wearable injectors tend to cost more and involve more user interaction, compared with the options above, so there needs to be a clear case to use them, such as a use case or viscosity or volume that other device options cannot support.

A few years ago, there appeared to be a trend towards high viscosity drug formulations (many tens of cP and above), primarily driven by new monoclonal antibody therapies. However, few of the

> "Designers of wearable injectors know that the device is the interface between the patient and the drug."

Figure 1: The Freedom60 syringe infusion system from KORU Medical Systems.

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very high viscosity drug formulations that were in development have been continued. Peers in pharmaceutical companies have said that manufacturing very high viscosity formulations is challenging, for example filtering and dosing.

In addition, autoinjectors have been upgraded to deliver volumes greater than 1 mL. For example, Teva's antimigraine treatment, Ajovy (fremanezumab-vfrm) is available in the 2.25 mL capacity Ypsomed YpsoMate autoinjectors.[1] Mylan's EpiPen (epinephrine) stores 2 mL and other autoinjectors, such as Midas Pharma's (Ingelheim, Germany) NISInjector, can deliver 3 mL or more.

There remains a strong case for wearable injectors where:

- The stored volume is greater than 3 mL, even if less than 3 mL is delivered
- The timing of dosing is important, for example with Amgen's granulocyte colony-stimulating factor (GCSF) analog, Neulasta (pegfilgrastim), or
- The dosing regime is unusual, for example delivering drug from more than one container.

STRATEGIES FOR DESIGNING A WEARABLE INJECTOR

Designers of wearable injectors know that the device is the interface between the patient and the drug. Many user studies, questionnaires and surveys have shown that ease of use is high on the list of requirements for wearable injectors. This tends to promote the design of very compact form factors, which often need custom primary drug containers.

On the other hand, pharmaceutical companies are often reluctant to use non-standard primary containers. For wearable injectors, this means that the primary drug container is very often a standard pharmaceutical cartridge with a septum seal at one end and a standard plunger at the other.

Whatever the primary container, the designer has a fundamental choice to make: whether to push the drug out of the container or pull it out.

Most pushing concepts push a standard pharmaceutical plunger, such as with a telescopic or bending plunger rod. Some concepts push drug out of a non-standard drug container such as the Trevyent PatchPump (Figure 2) from United Therapeutics (Silver Spring, MD, US), which was developed by SteadyMed Therapeutics until 2018 when United Therapeutics acquired SteadyMed. The PatchPump uses an expanding battery to push drug out of a semi-flexible container. The advantages of pushing concepts include:

Figure 2: Trevyent PatchPump from United Therapeutics uses an expanding battery to push drug out of a semi-flexible container.

"There is no single wearable injector strategy or implementation that is ideal for all drugs and indications. Therefore, we can expect to see a mixture of strategies on the market."

- The drug does not contact different materials on its way to the patient
- There is minimal risk of damage to the drug
- No vacuum is created, which minimises the formation of air bubbles.

Pulling concepts tend to have some sort of reciprocating piston, or peristaltic or other pump between the drug container and the needle (or cannula). The advantages of pulling concepts include:

- The pump features can be physically separate from the container, which allows for different device layouts
- A single design of the pump module could support different primary drug containers such as vials, syringes or cartridges
- Some pumps can be used to pump in both directions, so the pump could fill the drug reservoir from a standard pharmaceutical vial before being attached to the body
- A pump could extract drug from more than one drug container.

There is no single wearable injector strategy or implementation that is ideal for all drugs and indications. Therefore, we can expect to see a mixture of strategies on the market.

THE CURRENT STATE OF WEARABLE INJECTORS

Here we present an update on selected wearable injectors, but cannot cover all of the devices in development.

West Pharmaceutical Services' SmartDose (see this issue, Page 36) was approved for Amgen's Repatha (evolocumab) (a 3.5 mL dose) in July 2016. Since then, West has:

- signed a development agreement with scPharmaceuticals (MA, US) for a 10 mL variant
- started offering a preloaded variant, and
- rolled out a fill-finish service.[2]

Insulet's (Acton, MA, US) Omnipod® Insulin Management System (Figure 3a) was repurposed for the delivery of Amgen's Neulasta as the Onpro on-body injector (Figure 3b) which was launched in April 2017.[3]

Enable Injections (see this issue, Page 28) has announced various development agreements for its enFuse platform with partners such as CSL Behring (King of Prussia, PA, US) and UCB (Brussels, Belgium). A transfer system which can pump drug formulation from a vial into the wearable enFuse injector is in development.

Figure 3: Insulet's Omnipod® Insulin Management System (a) was repurposed for the delivery of Amgen's Neulasta as the Onpro on-body injector (b).

In March 2020, SHL Medical acquired Weibel CDS, whose LyCaJect patch injector can reconstitute lyophilised drugs *in situ*. We have seen various handheld injectors that can reconstitute, such as Ypsomed's LyoTwist platform, but it is unusual to see explicit support for lyophilised drugs in a wearable device. LyCaJect's drug delivery mechanism is purely mechanical (spring based) but electronic sensors monitor the injection and display progress.[4]

Ypsomed's YpsoDose is motor-driven and based on a standard 10 mL cartridge, which can be filled to lower volumes to support any injection up to and including 10 mL.

Subcuject (see this issue, Page 32) is developing a very small, prefilled, wearable injector that does not incorporate electromechanics. Instead, it is driven by salt-water osmosis which allows it to be compact and inexpensive. Subcuject is performance testing a moulded concept model of the device in order to demonstrate stability of the base technology.

Sensile Medical's micropump system is based on a reciprocating rotor and has been approved for delivering apomorphine to treat Parkinson's Disease.[5] Sensile Medical, which was acquired by Gerresheimer in 2018, has been adapting the pump for various indications and drugs including under a strategic alliance with Sanofi and Alphabet subsidiary Verily Life Sciences (South San Francisco, CA, US), to develop and commercialise a connected insulin patch pump.[6]

In July 2020, Sorrel Medical (see thisissue, Page 20) signed a partnership agreement with an undisclosed pharmaceutical company to further develop its pump system,[7] and has opened a new cleanroom manufacturing site for the manufacture of hundreds of thousands of units per year.

Other companies that have publicly announced their wearable injector projects include Elcam Drug Delivery Devices, E3D (see this issue, Page 24), Phillips-Medisize (see this issue, Page 15), Becton Dickinson, Sonceboz, and CCbio (see this issue, Page 12).

PROGRESS ON INTERNATIONAL STANDARDS

ISO 11608-6 "Needle-based injection systems for medical use – Requirements and test methods – Part 6: On-body delivery systems" is still in development, currently in its enquiry phase. It is expected to:

- Define physical, functional, biological, electrical safety and software, and drug compatibility requirements
- Define test methods for adhesion of the injector to the body
- Give guidance on methods for measuring the dose profile
- Define methods for measuring needle or cannula displacement.

Meetings during most of 2020 have been postponed due to the covid-19 pandemic and the next meeting is unlikely to be held before March 2021.

A LOOK TO THE FUTURE OF WEARABLE INJECTORS

In our experience, all the pharmaceutical companies that are developing injectable drugs are considering wearable injectors in their device strategies. Anticipating this demand, all established injectable device manufacturers that we are aware of have at least one form of wearable injector in their portfolio. Additionally, there are many specialist wearable injector companies.

The use case and cost of wearable injectors mean that they are not likely to

"In our experience, all the pharmaceutical companies that are developing injectable drugs are considering wearable injectors in their device strategies. Anticipating this demand, all established injectable device manufacturers that we are aware of have at least one form of wearable injector in their portfolio."

replace prefilled syringes and autoinjectors. Yet wearable injectors do allow self-administered delivery of some drugs that would otherwise require clinical support and/or admission to a medical facility.

The device concepts which push drug from standard pharmaceutical cartridges are likely to feature strongly in the future marketplace, primarily due to risk aversion by pharmaceutical companies. Alternative devices will have a bright future where they can demonstrate an advantage such as a smaller or more elegant form factor or better usability.

ABOUT THE COMPANY

Springboard specialises in developing devices from concept to manufacture for regulated markets. The company is expert at creating innovative yet robust designs and solving difficult technical problems quickly. Springboard does not have internal projects so it is as fast and cost effective as possible, and the intellectual property belongs to its clients.

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ABOUT THE AUTHOR

Tom Oakley leads engineering and scientific teams developing new injection devices, pumps and inhalers. He has been the named inventor on dozens of patents throughout his 20 years' experience in industry. Mr Oakley is a regular speaker at various international conferences on innovation and medical device development, and mentors engineering and MBA students on innovation and device development at the Cambridge University Engineering Department and the Judge Business School. He read Engineering at Cambridge University (UK) before becoming the Choate Fellow in Human Physiology and Pathology at Harvard University (Cambridge, MA, US).

YPSOMED
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SIMPLIFYING LARGE-VOLUME PATCH INJECTION FOR PHARMA AND PATIENTS

In this article, Reto Jost, Innovation and Business Development Manager at Ypsomed, provides an update on the YpsoDose platform and its importance as the driver for the business unit's new patch injector franchise.

A NEW PLATFORM PRODUCT

Whether pharma is developing its own internal platform or sourcing from an original design and manufacturing company such as Ypsomed, the selection of a device platform has become standard practice during the development of parenteral drugs. The key benefits of leveraging a platform, such as shorter time-to-clinic, lower up-front investments and lower project risks, are driving the device selection process and are highly valued by pharma partners. Ypsomed has a strong track record of developing self-injection device platforms, including reusable pens, prefilled pens and prefilled autoinjectors. The new patch injector franchise is no exception.

For all of Ypsomed's devices to date, the primary drug container – either the pen cartridge or prefilled syringe – was generally available on the market and well characterised. A critical aspect of developing YpsoDose as a new platform device was to define the platform development scope as early as possible, in conjunction with a new cartridge-based primary drug container that leverages existing components wherever possible. The following sections outline key development aspects of the YpsoDose platform, which is being industrialised for clinical and commercial use.

> "Simplicity and safety are key requirements for a patch injector, and are reflected in the design of YpsoDose."

SIMPLICITY AND SAFETY

For patch injector platforms, simplicity and safety are key. The main drug candidates for large volume injectable drugs are antibody-based treatments for autoimmune diseases, including orphan and rare diseases. Looking into the future, patch injector demand will increase further to cover the subcutaneous delivery of immuno-oncology drugs. Therefore, the potential range of indications suitable for patch injectors covers both clinical and home settings, from young to elderly patients, with varying degrees of symptoms and disabilities.

Patch injectors are dosed subcutaneously every two weeks, monthly or even less frequently. The number of use steps, and thus complexity, must be minimised to ensure that all users will remember the correct handling even with a longer timespan between injections. Accordingly, simplicity and safety are key requirements for a patch injector, and are reflected in the design of YpsoDose. The patch injector is prefilled and preassembled, therefore reducing the handling to two simple steps: patch and inject. The digital user interface ensures clear and unambiguous communication of the device status to the user. The integrated skin sensing patch guarantees needle safety even in case of false manipulations by the user, such as early activation of the start button or premature removal of the device from the skin (Figure 1).

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"YpsoDose guides the patient to know when to push the injection button and provides feedback throughout the injection process. At the end of the injection, the needle is retracted and YpsoDose is ready for disposal or specialist recycling."

Figure 1: YpsoDose attached to a participant's abdomen during simulated use testing.

EXCELLENT USABILITY

Ultimately, to ensure the broad adoption of patch injectors for biological therapies, usability is the most important aspect that needs to be tested with healthcare professionals (HCPs) and patients. Current offerings are typically HCP or patient-filled or assembled. However, no prefilled, ready-to-use wearable devices are currently approved for patient use. Ypsomed has performed several rounds of human factors work to optimise the user interface. Key aspects at the beginning were simplicity of user steps and device feedback.

In the meantime, human factors work with YpsoDose has been completed with final adjustments to the patch system and user interface. The YpsoDose handling steps are similar to those of a two-step autoinjector: remove the cap and inject. For YpsoDose this is simply patch and inject. YpsoDose guides the patient to know when to push the injection button and provides feedback throughout the injection process. At the end of the injection, the needle is retracted and YpsoDose is ready for disposal or specialist recycling.

EASILY CUSTOMISABLE FOR A BROAD RANGE OF APPLICATIONS

The flexible electromechanical design of YpsoDose enables easy customisation for a broad range of applications. Different fill volumes, flow rates and viscosities are simply accommodated by re-configuring the software and modifying components linked to the cartridge fill volume. This is not only advantageous when seeking a solution for a particular drug product, but it is even more relevant when pharmaceutical customers are selecting a patch injector for multiple drug candidates or fill volumes.

PROVEN CARTRIDGE AND BESPOKE NEEDLE UNIT TECHNOLOGY

A key development aspect is the ability to prefill and maintain the sterility of the drug reservoir and fluid path during the lifetime of the device. For larger injectable volumes, patch injectors require a new drug reservoir, and the prefilled cartridge is the drug container of choice for pharma. Cartridges are well characterised and utilise established materials, components and filling processes. They also have excellent container closure integrity and drug compatibility properties. The cartridge does not interact with the rest of the YpsoDose injector until the actual start of injection. As a cartridge does not have an integrated fluid path and needle, YpsoDose incorporates a bespoke sterile fluid path enclosed within the sterilised needle unit. The connection between the cartridge and fluid path/needle unit is completed only on injection.

END-TO-END OFFERING

The standardised interface between the 10 mL cartridge and needle unit is designed to allow the cartridge to be filled on conventional filling equipment using ready-to-fill tub formats. Ypsomed is working closely with partners to ensure that standard components and processes are compatible with the YpsoDose device:

- The 10 mL glass cartridge is compatible with standard 13 mm coated vial stoppers and 20 mm coated plungers
- The precrimped cartridges are supplied in a standard 3" tub format compatible with established filling processes
- Pharma companies, or their chosen CDMO, partners undertake cartridge characterisation and filling work.

Ypsomed has worked closely with its ready-to-fill cartridge, filling and final assembly partners. Drawing on its partners' expertise, the company is able to provide an end-to-end solution. Final assembly, a critical step in the supply chain, is being prepared with established equipment partners and with one of Ypsomed's CDMO partners. This holistic approach not only allows the company's customers to reduce time-to-clinic, but also enables pretesting and preverification for each drug variant, thus reducing project-related risks.

LARGE VOLUME PATCH INJECTORS – A NEW SELF-INJECTION DEVICE CLASS

The evaluation and selection of wearable patch injectors continues to compete against more frequent dosing with standard prefilled syringe-based autoinjector therapies. And, for pharma companies to consider and

"As a cartridge does not have an integrated fluid path and needle, YpsoDose incorporates a bespoke sterile fluid path enclosed within the sterilised needle unit. The connection between the cartridge and fluid path/needle unit is completed only on injection."

invest in patch injectors, they need to be able to access reliable device technology, utilise standard filling processes based on a full understanding of patient and HCP preferences. Fulfilling these requirements with well thought out device technology will allow the patch injector market and the YpsoDose franchise to grow significantly over the coming years, and to become established as the third self-injection device class, and complement the maturing markets for pens and autoinjectors. The 10 mL YpsoDose has undergone thorough internal testing and comparative studies with pharma customers and Ypsomed is committed to the successful industrialisation and commercialisation of YpsoDose as a new state-of-the-art patch injector (Figure 2).

Figure 2: YpsoDose, the prefilled electromechanical motor-driven patch injector.

YPSODOSE PATCH INJECTOR OVERVIEW

Developing and designing a wearable patch injector is demanding and requires a broad range of technology and medical device competencies. Ideally, the infrequently used patch injector should be as easy, if not easier, to use as a disposable two-step autoinjector, which is why the prefilled YpsoDose format incorporates the key technical features and benefits detailed in Box 1.

ABOUT THE COMPANY

Ypsomed is a leading independent developer and manufacturer of both mechanical and connected autoinjector and pen injector systems for self-administration. The company's customisable product platforms cover autoinjectors for prefilled syringes in 1 mL and 2.25 mL format; disposable pens for 3 mL and 1.5 mL cartridges; reusable pens that include automated injection mechanisms; and ready-to-use prefilled patch injectors. Unique click-on needles and infusion sets complement the broad self-injection systems product portfolio. Ypsomed provides its partners with excellent technological expertise and full regulatory support for the device relevant aspects of the registration process.

The injection systems are developed in Switzerland with strong in-house competencies covering concept and product development, tool-making, injection moulding and automated assembly. Ypsomed is ISO 13485 certified and all processes are run according to design control and cGMP guidelines with operational QA/QC experts on-site at each location. Ypsomed's US FDA-registered manufacturing facilities in Switzerland, and a new facility in Germany, are regularly inspected by both pharma customers and regulatory agencies to supply devices for global markets, including US, Europe, Japan, China and India. Ypsomed has more than 35 years' experience and well-established working relationships with numerous leading pharma and biotech companies.

BOX 1: YPSODOSE KEY TECHNICAL FEATURES AND BENEFITS

- Prefilled and fully disposable to remove any need to assemble or fill the drug reservoir and device.
- Adheres to the skin during injection and is easy to remove after injection.
- A capacitive sensing patch, which only allows initiation of the injection after the skin sensor has confirmed skin contact.
- Automatic needle insertion at the start, and retraction at the end, of the injection process. The needle is also retracted if the device is removed from the skin before the end of injection.
- An electromechanical drive accommodates a range of fill volumes and viscosities and provides a programmable and reproducible injection time and volumes for each drug.
- Audible and visual feedback to clearly communicate with the user before, during and after the injection.
- The integrated electronics allow wireless connectivity to provide additional smart services.

ABOUT THE AUTHOR

Reto Jost is Innovation and Business Development Manager with Ypsomed Delivery Systems. He has been with Ypsomed since 2014 in a number of roles in product management and business development, working with pharma companies to develop and bring to market innovative self-injection systems. Since 2018 his main focus has been on new product innovation, with particular focus on YpsoDose. He holds an MSc in Mechanical Engineering from ETH Zurich, Switzerland, and a CAS in Business Administration from HES-SO, Fribourg, Switzerland. Mr Jost has broad experience in medical devices, having worked in the industry since 2006.

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TECHNOLOGY SHOWCASE: CCBio's QuickDose

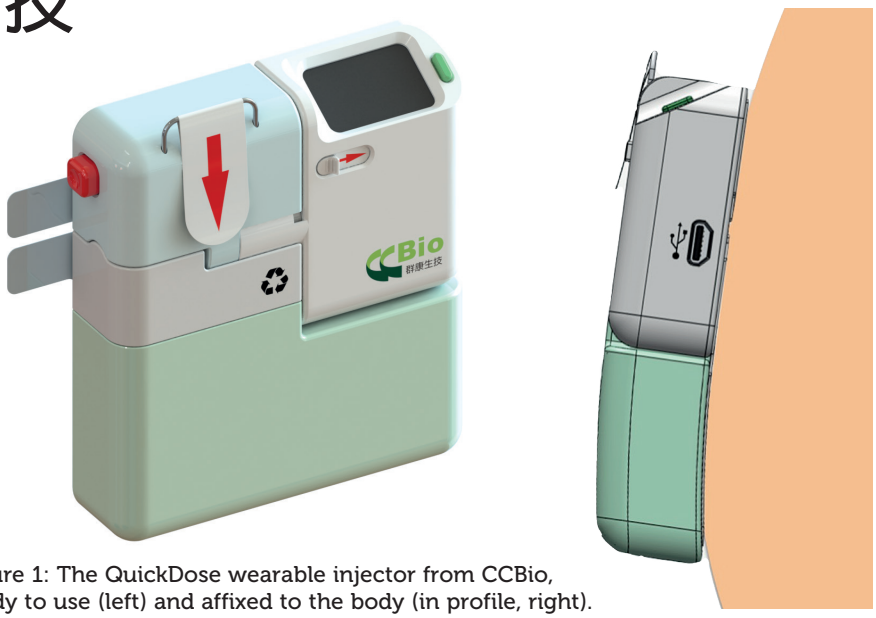

Figure 1: The QuickDose wearable injector from CCBio, ready to use (left) and affixed to the body (in profile, right).

CCBio is introducing a new era of wearable on-body medical devices. QuickDose (Figure 1), recently successfully developed with both patients and pharmaceutical industry partners in mind, contains all the necessary elements for an excellent on-body device, comprising three major technical achievements:

- Container
- Needle Set
- Delivery Unit.

The Container (Figure 2a) is extremely flexible, can be configured for dose volumes from 5 mL to 250 mL, and uses a soft and comfortable polymer mini-bag system. It provides users with many different options for customisation.

The Needle Set (Figure 2b) is easy to use, maximising patient convenience and comfort by penetrating the skin with both a steel and a soft needle simultaneously, then gently retracting the steel needle once the soft needle is in place. The Needle Set's well-tuned mechanism reduces the pain experienced by the user.

The Delivery Unit (Figure 2c) is the "jewel in the crown" of QuickDose. It incorporates various advanced technologies, including options for WiFi, near field communication (NFC) and Bluetooth connectivity, an LED display, fully-customisable programmability, a powerful server motor and a lithium battery.

The Delivery Unit is capable of handling variable dose volumes and concentrations, different drug viscosities and different injection speeds and times. Its smart program functionality can help patients take control of their treatment, making

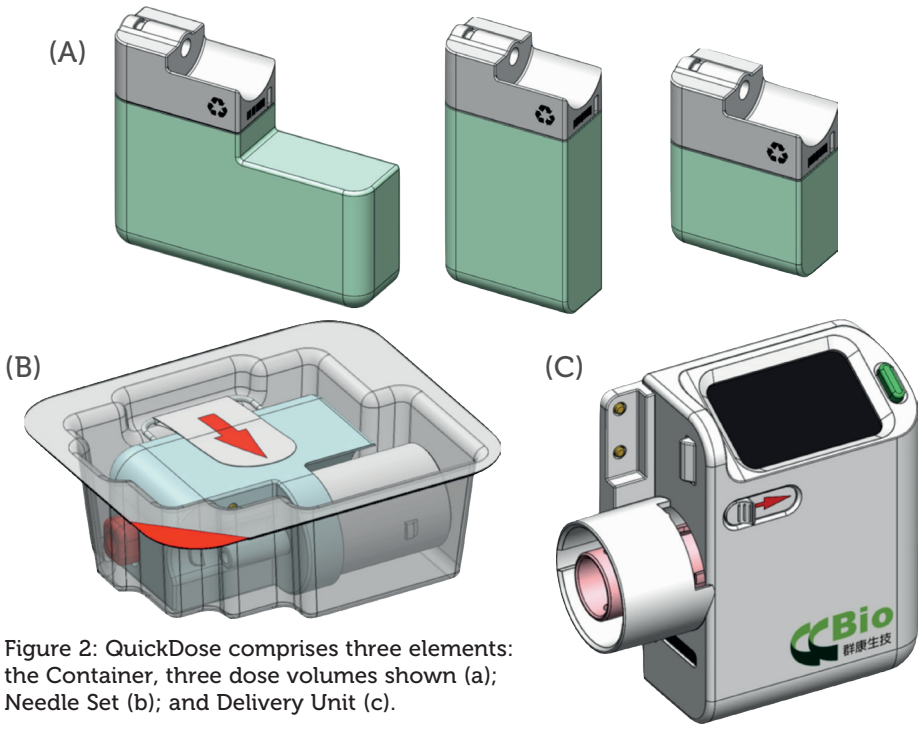

Figure 2: QuickDose comprises three elements: the Container, three dose volumes shown (a); Needle Set (b); and Delivery Unit (c).

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"With QuickDose, in addition to the treatment experience being more acceptable and patient friendly, the cost of therapy also becomes more acceptable and patient friendly too."

their daily life easier and more comfortable, and reducing the need for hospital visits and involvement of healthcare providers.

The three elements fit together as shown in Figure 3.

Moreover, with QuickDose, in addition to the treatment experience being more acceptable and patient friendly, the cost of therapy also becomes more acceptable and patient friendly too.

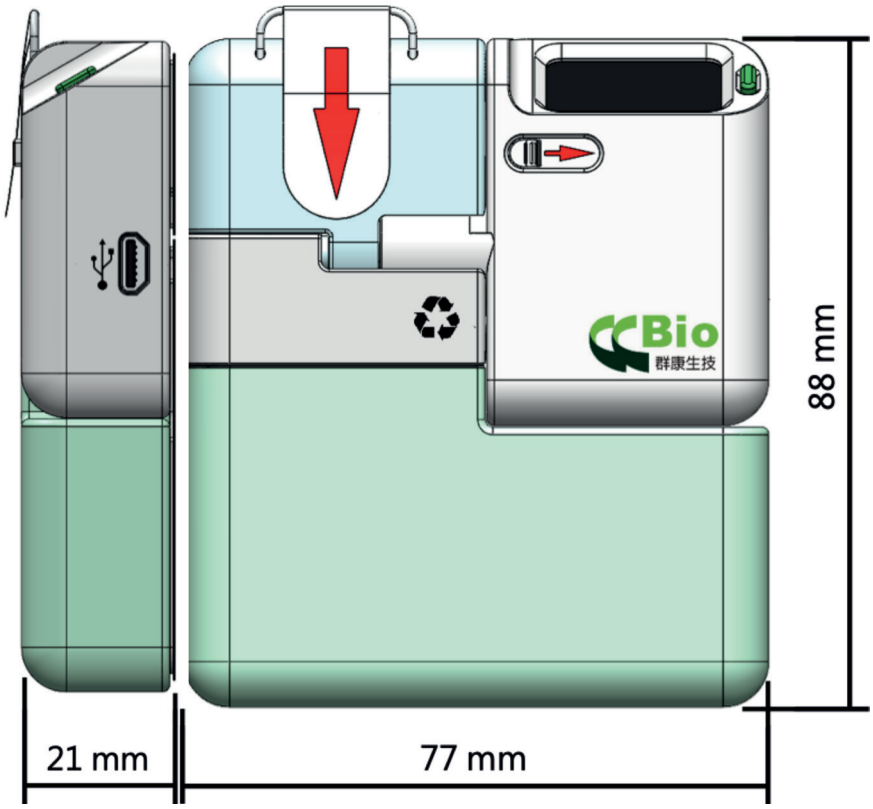

Figure 3: The Container, Needle Set and Delivery Unit fit together to form the complete the device.

CCBio is an experienced, skilled and well-established medical device designer and manufacturer based in Taiwan, with all the core competencies and capabilities required to offer combination products, medical devices and medical containers to pharma partners and, ultimately, patients. These core competencies include tooling, moulding, assembly, testing, verification, validation, R&D and regulatory affairs and pharmaceutical testing. Crucially, these capabilities are all in-house, meaning customers benefit from a one-stop solution to save valuable time and reduce costs, making CCBio designs and products highly competitive and price accessible.

The meaning of CCBio's slogan "Consistently Care By Innovation" is to provide high-quality yet affordable medical devices through rapid innovation within our design and R&D teams. We continue our philosophy of consistent care with our robust manufacturing processes, never compromising on product quality. The result is that we offer medical devices of the highest quality that truly meet patient needs.

"Core competences include tooling, moulding, assembly, testing, verification, validation, R&D and regulatory affairs and pharmaceutical testing."

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EMERGING TRENDS IN WEARABLE DRUG DELIVERY

In this article, Tony Bedford, Director, Front-End Innovation, Phillips-Medisize, discusses the current state of the fledgling on-body injector market, including the difficulties of competing with autoinjectors in the <5 mL space, the potential on-body injectors have in oncology and Phillips-Medisize's own developments in the on-body injector field.

Even prior to the launch of the first wearable injector outside of insulin, the drug delivery industry has been anticipating significant uptake in the use of such novel devices, with forecast compound annual growth rates of over 25% for the next ten years.[1] In reality, the on-body injector (OBI) market for non-insulin is a fledgling, experimental one, and we are yet to see a consistent trajectory that it will follow, with only two "true" wearable (non-insulin) devices on the market and no new product launches since 2016.

Even the nomenclature used to describe wearable injectors seems to be suffering from an identity crisis, with multiple acronyms and descriptors being used – large volume injector (LVI), patch pump, OBI (as used in this article) and on-body delivery system (OBDS), which has been adopted for an upcoming standard by the ISO,[2] to name but a few.

"Even the nomenclature used to describe wearable injectors seems to be suffering from an identity crisis, with multiple acronyms and descriptors being used."

AUTOINJECTORS ERODING POSSIBLE OBI MAKET SHARE

With that reality check stated, we can speculate on a few emerging trends that might allow this new breed of subcutaneous drug delivery device to carve out a niche for itself, beginning with a potential increase in the likely "sweet spot" volume of drug to be delivered. A number of OBIs in development have focused on volumes below the 5 mL mark, but the likelihood of their widespread adoption is seemingly being eroded by a steady increase in the popularity of self-administered autoinjectors and, in particular, the advent of autoinjectors capable of delivering up to 2.25 mL of liquid.

"A number OBIs in development have focused on volumes below the 5 mL mark, but the likelihood of their widespread adoption is seemingly being eroded by a steady increase in the popularity of self-administered autoinjectors."

Anecdotally, it is feasible for a patient to receive two consecutive

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doses from 2.25 mL autoinjectors provided sufficient training and instructions are in place, although questions remain with respect to the practicalities and patient comfort of doing so. Issues that may need to be overcome include:

- Ensuring that patients are sufficiently trained to use both autoinjectors (in the case of a pack of two equalling a single dose) rather than mistakenly considering one to be a spare.
- Avoiding under-dosing through wet injections (where the autoinjector is lifted away from the skin prior to completion of delivery).
- Absorption and pain issues caused by repeated injections at the same site.

These issues could be addressed through the use of an OBI. Nevertheless, the availability of proven autoinjector technology may make <5 mL a challenging playing field for OBIs. That said, there may be plenty of opportunities for delivering volumes in excess of 5 mL, and one such opportunity is emerging in immuno-oncology.

FROM INTRAVENOUS TO SUBCUTANEOUS

For some time, the possibility of switching drug formulations from intravenous (IV) to subcutaneous (SC) delivery has been considered to be a driving force for the OBI market, as the volumes resulting from such a switch are likely to be much higher than any autoinjector or prefilled syringe can accommodate. That said, there is a precedent in oncology for nurse-administered delivery of SC drugs from a large syringe, for example MabThera SC 1400 mg (Roche, Basel, Switzerland), which is delivered as a fixed dose of approximately 11 mL. Although evidence of this type of switching is limited, there are some eye-catching programmes in early-phase clinical trials.

A small number of successfully launched PD-1 and PD-L1 "checkpoint inhibitors", intravenously delivered anti-cancer drugs that stimulate the immune system, have undergone positive Phase I research evaluating a switch to an SC formulation. This includes Merck & Co's (Kenilworth, NJ, US) Keytruda (pembrolizumab) which is already one of the best-selling drugs globally – and with further approvals likely, Keytruda's revenue is set to increase well beyond the US$11.1 billion (£8.3 billion) achieved during 2019.[3] At this early stage, an accurate prediction of SC liquid volume is not possible, but estimates in the 5–20 mL range are entirely plausible for this and other reformulated SC drugs in this category, making them prime candidates for administration via OBI devices that can accommodate and deliver these larger payloads.

COVID-19 AND ONCOLOGY

The ongoing and seemingly open-ended uncertainty caused by the covid-19 pandemic may also influence the direction of travel for oncology drugs and wearable drug delivery devices. Cancer patients have been finding their surgery or treatment postponed or even cancelled as healthcare providers pool their resources to fight the coronavirus,[4] whilst some patients will have chosen to stay away from clinics simply because of the risks involved. Although it is probably too early to tell what the impact of this situation is, it is likely to result in an increased number of tragic outcomes.

In the UK, NHS England has rolled out a programme permitting convenient, non-hospital based treatments for cancer patients,[5] which could be an early indication of the type of changes that come to pass in healthcare provisioning as a result of covid-19. One such change could be the adoption of OBIs for the delivery of oncology drugs; aside from the aforementioned MabThera there are other cancer treatments already available for SC administration in addition to the checkpoint inhibitors and other maintenance therapies currently undergoing clinical trials. Deploying these in an OBI could help mitigate pandemic-related risks through fewer touchpoints with frontline staff and less travel for patients, should the difficulties caused by covid-19 either stay with us for an extended period or facilitate a permanent change in the way we obtain certain healthcare provisions.

However, it must be acknowledged that the uptake of OBIs in the oncology sector is not straightforward; as with any healthcare practitioner, the protection afforded by oncologists to their patients includes maintaining the utmost safety in their treatment, as cancer drugs can be highly toxic and patients are often very unwell. Some cancer drugs demand direct supervision by a healthcare practitioner during at least the first course of treatment.

One advantage that OBIs could offer in this instance is the reduction of time spent in-clinic, with faster set-up times and shorter delivery durations than IV administration, whilst maintaining the increased safety that in-clinic treatment permits – or, for drugs considered suitable for self-administration, eliminating the requirement for the healthcare practitioner to be present altogether, along with the economic burdens associated with in-clinic treatment.

"A small number of successfully launched PD-1 and PD-L1 "checkpoint inhibitors", intravenously delivered anti-cancer drugs that stimulate the immune system, have undergone positive Phase I research evaluating a switch to an SC formulation."

PREFILLED OR USER-FILLED AND DEVICE COMPLEXITY

With the OBI market still in its infancy – at least as far as launched, marketed products are concerned – there is not much evidence to point to an industry "preferred" configuration. Devices launched (and in development) range from simple, spring-driven piston-based systems to sophisticated electromechanical solutions, and employ drug containers ranging from fill at point-of-use reservoirs to compatibility with standard primary containers.

From an automation standpoint, there is an obvious bias towards devices that are designed to use primary containers that are compatible with standard filling processes. Couple this to usability requirements, whereby minimal user interaction is considered preferable, and a clear trend is emerging for prefilled and preloaded devices offering a use sequence that is close to the simplicity of the two-step autoinjector.

Following that trend, Phillips-Medisize is currently engaged with a leading biotechnology company for the late-stage development of one such prefilled OBI for SC drug delivery. The electronic-enabled combination product comprises of a single-use disposable delivery device and prefilled container that can either be affixed to the patient's body via an adhesive patch or worn near the infusion site. The entire product is replaced every two days and more product launches of this nature are anticipated in the short-to-medium term.

> "Phillips-Medisize has been developing its own OBI device that addresses several of the trends thus far discussed."

Prefilled is by no means the only viable solution though – user-filled devices come with challenges of their own, as sterility must be maintained until the time of use – as a clear need for devices that are filled at the point of use is also emerging. The Neulasta® Onpro™ (Amgen, Thousand Oaks, CA, US), which launched in 2015 for post-chemotherapy neutropenia treatment, is a direct descendent of the user-filled Omnipod® device (Insulet Corporation, Acton, MA, US) for diabetics, and has shown that there is acceptance of reservoir-based OBIs, albeit for a very specific use case.

The potential for OBIs in the oncology sector, as covered in this article, could also present opportunities for fill-at-point-of-use reservoir-based devices. Stability concerns are reduced, as it is expected that the drug would not be in contact with the primary container or reservoir for sustained periods. This configuration would allow a healthcare professional to fill a device with a flexible weight-based dose, creating a need for bolus injectors that can fully evacuate a payload. Additionally, fill-at-point-of-use OBIs would permit lyophilised drugs to be delivered shortly after reconstitution.

PHILLIPS-MEDISIZE'S PROTOTYE OBI

Phillips-Medisize has been developing its own OBI device that addresses several of the trends thus far discussed (Figure 1). By incorporating electronically-enabled, delayed (if required) bolus delivery from a <1 mL reservoir, the delivery duration of Phillips-Medisize's OBI can be programmed to be from around 10 seconds up to 45 minutes without any need for changes to the drive system components. The device has been designed initially for fill-at-point-of-use with healthcare settings in mind – greater throughput, minimal contact time and the ability to administer away from clinic are all possible. However, Phillips-Medisize is exploring the possibility of a cartridge to suit the trend towards prefilled devices.

Currently at the prototype stage, the Phillips-Medisize device also addresses the trend towards increasing volumes, having been conceived with modularity in mind. The selected drive system is able to deliver a wide range of volumes and viscosities, the key variable being the duration of delivery set against absorption rates – for example, 5 mL of 20 cP liquid could be delivered in less than a minute.

Returning to the complexity of OBIs, it is inevitable that the more features and functions a device has, the higher the cost of goods will be. This will also be affected by the choice of drive system (including activation, drug expulsion and needle insertion). Predicting what may be an acceptable device cost is challenging, not least because each application is likely to come with a very different set of needs and parameters (such as unit volume manufactured, selling cost of the drug and the characteristics of the drug), but industry chatter does suggest that cost is a factor that has hampered the uptake of OBIs thus far. Consequently, the final trend

Figure 1: Philips-Medisize's OBI, which uses electronically-enabled delivery, is able to deliver a wide range of volumes and viscosities of SC formulation.

we must consider is the emergence of significantly lower cost OBIs that could heighten interest in this as-yet fledgling market by making them more competitive with autoinjectors for delivery volumes addressable by both device types. It certainly feels as though we are still at the beginning of an exciting journey.

ABOUT THE COMPANY

Phillips-Medisize, a Molex company, is an end-to-end provider of innovation, development, manufacturing and post-launch services to the pharmaceutical, diagnostics, medical device and speciality commercial markets. Post-launch services include a connected health app and data services. Backed by the combined global resources of Molex and its parent company Koch Industries, Phillips-Medisize's core advantage is the knowledge of its employees to integrate design, moulding, electronics and automation, providing innovative high-quality manufacturing solutions.

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ABOUT THE AUTHOR

Tony Bedford is Director, Front-End Innovation at Phillips-Medisize and has been involved in the design and development of medical devices for 25 years. With a background in product design, his broad experience covers everything from innovation and market strategy to clinical research and product launch, with a focus on understanding market, stakeholder and user needs. Prior to joining Phillips-Medisize, Mr Bedford held project management and business development roles in the consulting industry, working on a wide range of device programmes. He has specialised in drug delivery devices for a number of years.

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ANDREI YOSEF, CEO, SORREL MEDICAL

Andrei Yosef is Chief Executive Officer of Sorrel Medical, an Eitan Group company focused on the development and manufacture of wearable drug delivery solutions for easy and efficient self-administration. He is a recognised expert in drug delivery device technology and high-end development processes, having served in several executive positions at Q Core Medical – a developer of smart infusion systems for hospital and ambulatory care settings. Dr Yosef holds a PhD in Biomedical Engineering and an MA in Mechanical Engineering, both from the Technion – Israel Institute of Technology.

In this exclusive interview with ONdrugDelivery, Dr Yosef discusses Sorrel's differentiated electro-mechanical, connected wearable injection platform, and two exciting recent milestones for the company, the opening of a state-of-the-art manufacturing facility and the signing of a significant partnership with a large pharmaceutical company.

Q The wearable injectors space is crowded. Please provide an overview of Sorrel Medical's wearable device platform. How it is differentiated from other wearable injectors, and how does it help Sorrel's partners to differentiate their therapeutic products?

A Sorrel's wearable drug delivery platform (Figure 1) is designed to provide a patient-centric and partner-focused solution for the self-administration of large-volume and high-viscosity medications. The prefilled and preloaded device configuration encourages adherence to treatment therapies and reduces the risk of medication errors. Being primary container-agnostic enables us to collaborate with multiple pharmaceutical partners to meet specific drug delivery requirements.

Sorrel devices utilise an electro-mechanical pumping mechanism for accurate and controlled drug delivery. To overcome the inherent challenge of maintaining sterility in preloaded devices, we have implemented first-of-its-kind UV LED technology for disinfection at point-of-care, disinfecting the point of engagement between the primary container and the device's fluid path. Additionally, we have proprietary technology in place which provides a unique solution for drawing medication directly from a vial, while remaining prefilled and preloaded. This saves our partners significant time and risk, as our devices conform to the primary container of their choice.

> "Being primary container-agnostic enables us to collaborate with multiple pharmaceutical partners to meet specific drug delivery requirements."

Q Focusing in on the electrical/electronic aspects, can you describe how Sorrel came to the decision to go for an electro-mechanical device?

A With our origins in Eitan Group and the world of smart electronic infusion pumps – where we have had drug delivery devices on the market for over a decade in hospital and homecare environments – we were already familiar with the value of a controlled and accurate pumping mechanism, integrated with a series of sensors and completed with connectivity capabilities. We researched hundreds of target molecules to ensure that our platform could meet the requirements for a wide range of applications – whether high accuracy is needed over a long period, perhaps together with a more complex

> "We have proprietary technology in place which provides a unique solution for drawing medication directly from a vial, while remaining prefilled and preloaded."

Figure 1: Sorrel Medical's wearable drug delivery device platform.

treatment regimen (delayed treatment, changing flow rates, patient controlled boluses/ pauses); or if only a fast bolus injection is required.

Sorrel devices incorporate multiple smart sensors, including air and occlusion detection, needle positioning, on-body attachment and more. Combined with visual, audio, and tactile indicators, this guarantees a successful self-administration experience for patients.

Our devices also include integrated connectivity, via Bluetooth and near-field communication (NFC), allowing patients to share treatment data with relevant stakeholders. Not only can the treatment data be accurately captured and easily shared between the patient, their caregiver and healthcare provider, but valuable insights can also be obtained. This can be achieved at the patient level – as a doctor learns a patient's adherence levels and tolerability to specific medication regimens and adjusts accordingly; or collectively – looking at anonymised data from a patient population as a whole, which can produce valuable insights to pharmaceutical companies, insurers, governments and regulatory agencies.

On a project-by-project basis, we are in ongoing discussions with partners on how best and at what stage to utilise the treatment data, whether in clinical trials or a commercial product, via a smartphone app, desktop application, cloud connectivity and other channels.

Q What stage of development is the device at currently?

A Sorrel is developing a platform of wearable drug delivery devices, with different device configurations all based on the same technology. Each device is at a different level of development maturity, according to relevant collaborations in place and interest from our pharmaceutical partners.

> "We were very pleased to be able to announce our strategic partnership with a large pharmaceutical company earlier this summer."

> "Sorrel devices incorporate multiple smart sensors, including air and occlusion detection, needle positioning, on-body attachment and more... Our devices also include integrated connectivity, via Bluetooth and NFC."

We have a range of offerings, from a small 1 mL device up to 30 mL capacity, utilising cartridges and vials, currently at various stages of development including verification and validation, human factors testing, animal studies and clinical trials. By the end of next year, we expect to have a number of clinical studies behind us, with different partners.

Q Congratulations on successfully partnering with a top global pharma company in July. This achievement represents a clear endorsement both of the platform and Sorrel as a company by the industry. Please could you describe Sorrel's ongoing partnering strategy?

A We are fortunate to have received very positive feedback from the market over the past couple of years and we were very pleased to be able to announce our strategic partnership with a large pharmaceutical company earlier this summer.

Our partnering strategy is to have multiple collaborations in place in parallel, working on different device configurations and all based on the Sorrel platform technology. After introductions and engagement in an initial agreement, we generally proceed within a feasibility assessment structure. This allows our potential partners to familiarise themselves with the Sorrel technology and subsystems while testing devices in parallel. We then engage in a clinical and commercial supply agreement, customising our devices to a specific target molecule and patient population, supporting our partners in their usability studies, regulatory submissions, clinical studies and eventual commercial launch.

Q Can you outline Sorrel's business structure? How does the group's significant background infrastructure benefit Sorrel's partners?

A Sorrel Medical is one of three privately held companies operating in the drug delivery space, under Eitan Group. All three companies develop smart, electro-mechanical drug delivery devices, each focused on a slightly different market segment. After a decade of experience with infusion pumps with our sister company Q Core Medical, we were looking to expand our business into new markets. This led to the founding of Sorrel, to focus specifically on the wearable drug delivery space.

While much of our knowledge and expertise derives from experience gained from the Sapphire infusion system on the market, Sorrel has developed several innovative technological solutions to address the issues we've identified as critical in the wearable space.

As a group, our core strengths are: (1) R&D – technological innovations in the world of parenteral injections; (2) Quality and Regulations – a critical aspect of any medical device company; and (3) Manufacturing – an integrated part of any development project, keeping operations and high volume manufacturing in our design considerations from the get-go.

We bring these core strengths into all partnerships and collaborations, whether with the Sapphire infusion systems, the AvosetGo home infusion pumps, or the Sorrel wearable injectors. We have considerable experience in cross-functional collaborations with strategic partnerships over the years in Eitan Group, with points of input from our partners integrated throughout our development processes and procedures.

Q What's next for Sorrel?

A Having received increasing interest from pharmaceutical and biotechnology companies over the last few years, Sorrel is moving forward with a number of development projects. In the short term, we are focusing on strengthening existing partnerships through feasibility testing and moving on to clinical trials. To facilitate this, in July 2020, we opened a new state-of-the-art manufacturing facility

which enables us to increase production capability significantly, ahead of upcoming trials and eventual commercialisation.

ABOUT THE COMPANY

Sorrel Medical is a medical device development and manufacturing company focused on prefilled wearable, on-body injectors. Its technology platform, based on a robust patent estate, is prefilled and preloaded and intended for the subcutaneous delivery of biologics, biosimilars and small molecules (doses from 1-30 mL). It is suited for multiple configurations, molecules, and indications, and is digitally integrated with Bluetooth and NFC connectivity.

Sorrel is one of three privately held companies operating under the Eitan Group, all in drug delivery devices, including Q Core Medical, Avoset Health and Sorrel Medical. Q Core Medical develops and manufactures the Sapphire infusion system, on the market in both hospital and homecare environments. Avoset Health is developing a connected homecare infusion pump, available for pharmaceutical companies in a dedicated application configuration.

The joint experience shared amongst the Eitan Group's three companies, includes development, commercialisation and manufacturing of drug delivery products across the continuum of care, multiple US FDA approvals, market presence in >20 countries, and an R&D team with experience in parenteral drug delivery, accuracy, flow control, human factors and cybersecurity.

> "In July 2020, we opened a new state-of-the-art manufacturing facility which enables us to significantly increase production capabilities ahead of upcoming trials and eventual commercialisation."

SORREL medical

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MEETING THE NEED FOR HIGH-VOLUME DRUG DELIVERY WITH ON-BODY BOLUS INJECTORS

In this article, Tsachi Shaked, Managing Director and Chief Business Officer at E3D, argues that on-body injectors present a safe and viable solution for high-volume drug delivery.

As the covid-19 crisis continues, many regular hospital visits and scheduled surgeries have been cancelled or put on hold, due to concerns about over-burdened hospital resources as well as fear of infection. Many mandatory hospital visits can be eliminated with the use of an on-body bolus injector which can handle drug volumes of 3 mL and over.

> "An on-body injector that can deliver high-volumes and viscous drugs slowly over a predetermined period ensures easy handling, safety, reduced pain and leak-free delivery and represents a viable alternative to autoinjectors."

An established player in the injectable medications market, Elcam Drug Delivery Devices (E3D) is working to create on-body delivery devices for subcutaneous or intramuscular delivery of medications outside a clinical environment. Creating a convenient bolus injector for home use spares patients a tiring hospital trip. Instead, they can rest comfortably at home while the on-body injector does its job (Figure 1). As healthcare resources are stretched increasingly thinly, it can provide welcome relief by providing a cost-effective alternative to outpatient treatment.

Figure 1: E3D's on-body injector for home care use.

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WHY USE AN ON-BODY BOLUS INJECTOR?

For self-administration, the rule of thumb for the length of time a patient can hold an autoinjector is 15 seconds. Because injections of 3 mL and more can take longer than 15 seconds, using a self-administered injection means longer holding time. With much higher volumes, subcutaneous tissue is limited in its ability to handle the fast injection of large volumes – and injecting large volumes can result in the drug leaking as well as causing the patient unnecessary pain. An on-body injector that can deliver high-volumes and viscous drugs slowly over a predetermined period ensures easy handling, safety, reduced pain and leak-free delivery and represents a viable alternative to autoinjectors.

E3D's on-body bolus injector (OBI) (Figure 2) delivers bolus subcutaneous injections at the desired injection time, as cost-effectively as possible and with minimal need for patient intervention. It provides automated drug delivery in the familiarity, comfort and convenience of the patient's home, eliminating the risk of exposure to carriers of covid-19 or other infectious diseases. It's also likely to be well accepted by patients. Recent research has shown that patients are showing increasingly high satisfaction with self-administered antibiotics using antibiotic elastomeric pumps.[1]

Operating the OBI takes only four simple steps:

1. Peel off liner
2. Attach to skin at injection site
3. Press button to start injection
4. Peel off after injection completed.

Figure 2: OBI 5 mL.

> "Because the smart injector device can be configured for wireless communication, full monitoring of comprehensive injection data can be made available."

Its key features are:

- Sterile
- Prefilled, preloaded and ready to use
- Adjustable injection time
- Variable injection volumes – from 3 mL to 40 mL
- Audible and visual indications for injection start and end as well as injection progress
- Full control of injection states
- Needle safety – needle hidden at all times
- Injection data transmission.

Because the smart injector device can be configured for wireless communication, full monitoring of comprehensive injection data can be made available – the physician is able to monitor the patient status through a mobile app, ensuring that the dosage was administered in full at the correct time.

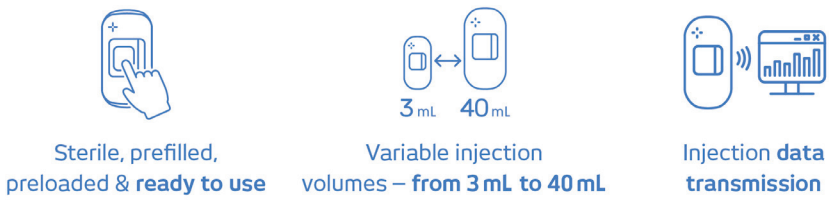

Figure 3: The OBI platform.

MAKING EARLY ADOPTION EASY

While there is often a small learning curve with autoinjectors, E3D addressed the usability issue by replicating a user experience already introduced to market. The preloaded ready-to-use OBI devices are easy to use. Key features considered during the design process included:

- User focused and ergonomic – the device can be easily applied to the patient's skin because of its size.
- Automated delivery – delivery of bolus injection (needle penetration) is automatically performed after being applied to the patient's skin and pressing the injection button.
- Stable attachment – device design and size ensure stable and safe attachment to the patient's body that cannot be easily dislodged.
- Simplified design – the device size has been reduced and the design simplified to enable cost-effective manufacture.

VERSATILE TECHNOLOGY PLATFORM

The OBI device technology platform (Figure 3) offers significant advantages in the delivery of other injectables, as it is cost effective, compact, light, inherently robust, economical and readily scalable

for any dose volume. The OBI platform can easily be scaled to deliver a liquid bolus of up to 40 mL. During early drug lifecycle development, dosage volume is frequently high. As development progresses, pharma companies are able to increase concentration and reduce dose volume. Since the device is well suited to delivering high-volume viscous liquids, it addresses an increasingly prevalent requirement for a versatile platform to accommodate the needs of emerging drug products.

THE FUTURE OF ON-BODY TECHNOLOGY

On-body injectors are set to represent an increasingly attractive alternative to handheld injector devices for higher dose volumes and viscous drugs. The compact, robust, flexible and cost-effective OBI platform can provide the required capabilities to meet the needs of specific drugs, therapies and patient populations, creating significant advantages for a broad range of drugs for a wide variety of indications including autoimmune conditions, oncology and multiple sclerosis.

Its versatility is set to provide significant added value to pharma companies seeking cost-effective on-body alternatives for large-volume and/or high-viscous drug applications. With more injectables requiring high dose volumes and with more of these drug products having elevated viscosities, on-body injector devices will have an increasingly important role to play in providing effective, safe and convenient patient care.

> "The OBI is another step in E3D's quest to free patients from having to visit hospitals."

Figure 4: E3D's range of products.

Most importantly, the OBI is another step in E3D's quest to free patients from having to visit hospitals, especially as the impact of the coronavirus crisis continues to be felt the world over (Figure 4).

ABOUT THE COMPANY

The Elcam Drug Delivery Devices (E3D) portfolio encompasses a wide range of injectables produced in the company's manufacturing facilities in Europe, the US and Israel. These devices include single- and multi-use, spring-powered autoinjectors designed for 1 mL and 2.25 mL prefilled syringes; wearable injectors for bolus, high-volume and viscous drug delivery; electromechanical and mechanical "smart" injectors with wireless connectivity; autoinjectors for viscous formulations; emergency-use injector devices; and injectors with both automated and manual reconstitution for lyophilised products.

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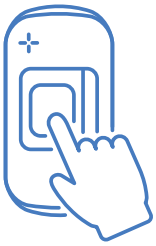
ABOUT THE AUTHOR

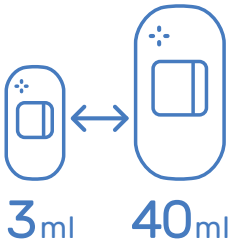
Tsachi Shaked is the Managing Director and Chief Business Officer at E3D, a subsidiary of Elcam Medical. He holds an MBA from Bar-Ilan University (Israel), specialising in marketing. As part of the company's portfolio, Mr Shaked is deeply involved with the development of E3D's new drug delivery devices incorporating connectivity and electronic applications. He has been with the company since 2006.

Elcam Drug Delivery Devices

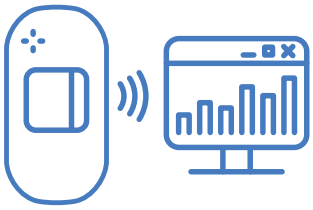
Meeting the Need for High Volume Drug Delivery with On-Body Bolus Injectors



Sterile, pre-filled, pre-loaded & **ready to use**



Variable injection volumes — **from 3ml to 40ml**



Injection **data transmission**

THE NEW PATIENT-CENTRICITY

In this article, Jennifer Estep, Associate Director, Marketing, Enable Injections, discusses the new pressures put on the healthcare system by the covid-19 pandemic, and how patients and healthcare providers alike are turning to patient-centric solutions to minimise risks and ease burdens. In particular, Ms Estep looks to the role large-volume wearable injectors could play in facing the challenges presented by the "new normal".

The term "patient-centric" has taken on new meaning in recent months due to the covid-19 pandemic. For many healthcare-related companies, patient-centric means "a focus on the needs of the patient". But with pandemic measures in place, patient needs have expanded, and the industry – medical device and pharma companies, healthcare providers, payers and other key stakeholders related to a patient's care – must adapt to these increased patient needs.

PATIENT EXPOSURE

At the onset of the pandemic, the risks for patients receiving care increased overnight. Locations patients had relied on to receive care, such as hospitals, became high-risk centres where they might acquire covid-19, and healthcare workers formerly devoted to administering routine care were no longer available for non-acute care.[1] Therefore, the pandemic situation prompts the question: in the new normal, should the term "patient-centric" now inherently include allowing a patient to have their healthcare needs met from their home without in-person interaction?

"At the onset of the pandemic, the risks for patients receiving care increased overnight. Locations patients had relied on to receive care, such as hospitals, became high-risk centres where they might acquire covid-19, and healthcare workers formerly devoted to administering routine care were no longer available for non-acute care."

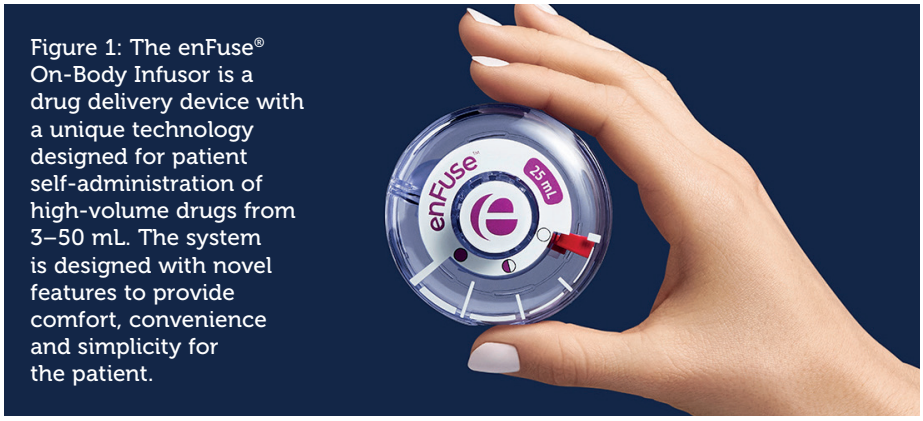


Figure 1: The enFuse® On-Body Infusor is a drug delivery device with a unique technology designed for patient self-administration of high-volume drugs from 3–50 mL. The system is designed with novel features to provide comfort, convenience and simplicity for the patient.

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"Large-volume wearable injectors, such as Enable's enFuse® On-Body Infusor, are likely to be essential elements making this extensive positive shift in healthcare possible, especially on the accelerated timescale mandated by pandemic conditions."

Due to covid-19, changes in the healthcare system have occurred in a fraction of the usual time. From the patient perspective, Medicare reports a surge in US telehealth visit numbers – from 13,000 beneficiaries pre-pandemic to nearly 1.7 million beneficiaries in the final week of April 2020.[2] In hitherto unseen numbers, patients are turning to technology to enable telehealth visits with healthcare providers, which accommodate these new patient needs by allowing for the remote continuation of care.

The risk of exposure to covid-19 has prompted change from the healthcare provider side as well, including the need to protect patients from exposure at healthcare facilities and prioritise keeping healthcare resources free for acute care. Because of these and other factors, some listed hereafter, large-volume wearable injectors, such as Enable's enFuse® On-Body Infusor (Figure 1), are likely to be essential elements making this extensive positive shift in healthcare possible, especially on the accelerated timescale mandated by pandemic conditions.

PATIENT BURDEN

Large-volume wearable injector technology may help to reduce patient burden in several ways (Figure 2). For example, large-volume wearable injectors can:

- **Enable patients to receive therapeutics at home**. Once a therapeutic has been formulated and approved for subcutaneous administration, a patient may be able to self-administer their prescribed therapeutic via a large-volume wearable injector in their home, whereas they would have previously needed to have their therapeutic administered in a healthcare facility via intravenous administration.
- **Reduce the need for a healthcare worker to administer care**. The demand for healthcare workers has increased with covid-19. Large-volume wearable injectors may reduce, or even eliminate, the need for healthcare workers to administer infusions, therefore making them available for urgent covid-19-related care.
- **Reduce patient and healthcare worker exposure**. Healthcare workers, patients and caregivers are all exposed when infusions are conducted in person. Even for situations with a home-infusion set up, a healthcare worker typically has to enter a patient's home and spends hours in close contact with them during the infusion. Large-volume wearable injector technology has the potential to reduce the need for in-person administration, which reduces the exposure for all involved.
- **Reduce the need for patients to leave the home for their healthcare needs**. A large-volume wearable injector has the potential to be shipped directly to a patient's home.
- **Communicate data automatically through digital technology**. Telehealth-enabled infusion devices allow a patient's data to be communicated directly with key stakeholders involved in their care. A large-volume wearable injector with digital communication technology would potentially allow the healthcare provider, and others involved in a patient's care, to receive updates on the patient's infusion, as well as reportable metrics which may verify infusion information and patient adherence.
- **Reduce the financial burden of therapy**. The needs of a patient also extend to their financial burden. By reducing the need for expensive visits to a healthcare facility for infusion, large-volume wearable injectors have the potential to provide economic benefits for the patient and payer, in addition to the healthcare benefits already discussed.

AN ECONOMIC MODEL

Enable Injections has worked with experts in healthcare decision modelling to develop an interactive model that can be used to evaluate the budget impact and cost-effectiveness consequences of an at-home wearable injector. The model assumed the ready availability of an at-home wearable injector that enables subcutaneous self-administration of high-volume therapeutics. Specifically, the model was designed to demonstrate the potential economic value of introducing a large-volume wearable injector for patients who previously received intravenous treatment for a selected indication, in this case, rheumatoid arthritis.

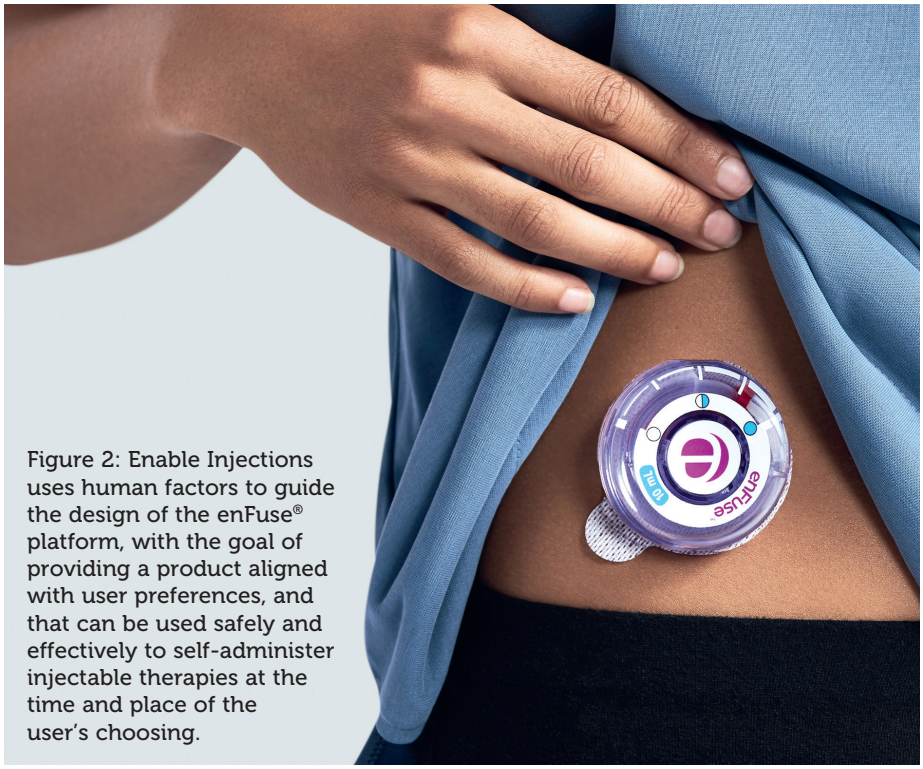

Figure 2: Enable Injections uses human factors to guide the design of the enFuse® platform, with the goal of providing a product aligned with user preferences, and that can be used safely and effectively to self-administer injectable therapies at the time and place of the user's choosing.

"For a hypothetical payer, with 1,000 patients receiving intravenous treatment for rheumatoid arthritis, the model shows the introduction of a large-volume wearable injector represents cost savings greater than 35%, or around US$2,000 in cost savings per patient per treatment month."

The model was based on published peer-reviewed literature to provide a broad, evidenced-based overview, including the clinical, cost and humanistic benefits of non-institutional therapeutic infusion. The literature search identified 878 unique articles, 63 of which were accepted for inclusion in the review and adopted for the model.

The Economic Takeaway

For a hypothetical payer, with 1,000 patients receiving intravenous treatment for rheumatoid arthritis, the model shows the introduction of a large-volume wearable injector represents cost savings greater than 35%, or around US$2,000 (£1,509) in cost savings per patient per treatment month. These savings result from a significant decrease in the costs of infusion services[3]from facilities, supplies and labour. Significant cost savings like these would undoubtedly benefit both the patient and payer.

PATIENT-FOCUSED

Enable Injections' goals have always been driven by the needs of patients. The enFuse® user has been front and centre throughout design and development of the technology, with the goal of meeting patients' wants, needs and preferences. This philosophy is evident in the design of enFuse®; for example, enFuse® is designed for ease of filling via the automatic vial transfer system at the time of use (Figure 3). Clinical feedback has been positive on the enFuse®, which provides validation that it is on track to achieve the aims of supporting superior outcomes, delivering an exceptional patient experience and driving improved healthcare value and economics.

Especially during the covid-19 pandemic, Enable Injections is staying focused on its goals. The "new normal" places renewed focus on the crucial benefits of self-administered at-home care. Enable Injections strives to embrace the new patient-centricity by providing a solution for patients. Now, more than ever, it is imperative that the industry puts the needs, wants and preferences of the patient first and embraces the new patient-centricity.

Figure 3: Using the automatic vial filling system, the user simply inserts the vial into the system, and the vial's entire contents are automatically transferred with no further user input.

ABOUT THE COMPANY

Enable Injections is an investigational-stage medical device company based in Cincinnati. It is developing and manufacturing on-body subcutaneous infusion delivery systems designed to help improve the patient experience, support superior outcomes and improve the healthcare system's value and economics. Enable's body-worn enFuse® drug delivery platform uses standard container closure systems to deliver large-volume, high-viscosity pharmaceutical and biopharmaceutical therapeutics.

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ABOUT THE AUTHOR

Jennifer Estep serves as Associate Director, Marketing for Enable Injections. She has more than 20 years of experience with marketing and strategy in the media, electronics and pharmaceutical industries. Jennifer earned a Bachelor of Science in Mechanical Engineering from Purdue University (West Lafayette, IN, US).

Patient-First Anywhere Care. enFuse®

enFuse® An innovative on-body infusor.

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Subcuject

STABILITY OF A WEARABLE INJECTOR POWERED BY OSMOSIS

Here, Jesper Roested, CEO, Subcuject, and Tomas Gundberg, Design Engineer Consultant, present engineering test data on Subcuject's wearable bolus injector, based on an osmotic drive system, demonstrating that the device presents a solution to the need for an inexpensive, mass-producible wearable injector.

THE FIELD OF WEARABLE BOLUS INJECTORS

The up-and-coming field of wearable injectors for injection volumes over 1.5–2 mL can presently be differentiated into two broad categories:

- High-end wearables that use electromechanical drive systems and commonly come with connectivity options, at the expense of relatively high complexity, high cost and large size.
- Low-end user-fillable wearables that are small and suitable for non-predefined injection volumes.

These two categories leave a clear gap in the market. Similar to the autoinjector space, the available wearable product range lacks a prefilled, simple-to-use and inexpensive wearable bolus injector designed to fill the role of a low-end product to be produced in bulk.

> "An ideal wearable injector must be acceptable to wear whilst attached to the body, which calls for a small size and that the product is as easy to prepare, activate and dispose of, as with a prefilled autoinjector."

> "Similar to the autoinjector space, the available wearable product range lacks a prefilled, simple to use and inexpensive wearable bolus injector designed to fill the role of a low-end product to be produced in bulk."

Subcuject is developing such an inexpensive, prefilled wearable injector, based on osmosis as the driving force. It is now demonstrated that the base technology is indeed a feasible product, delivering consistent performance and that endures viscosities up to at least 100 cP.

THE COMPLICATIONS OF DEVELOPING A LOW COST, PREFILLED WEARABLE INJECTOR

A wearable bolus injector is characterised as a subcutaneous injection device that is attached to the body for the duration of an injection, often several minutes, during which the drug is injected at a low flow rate in order to avoid pain. The viscosity of the injected drug is often high, and one of the challenges in developing a wearable injection device is that the delivery mechanism requires quite a high amount of energy, which must be stored for the device's shelf-life. A further complication is that the energy must be released slowly and deliberately during injection. An ideal wearable injector must be acceptable to

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wear whilst attached to the body, which calls for a small size and that the product is as easy to prepare, activate and dispose of, as with a prefilled autoinjector.

In order for a wearable injector to be commercially viable in volume, it also needs to be as inexpensive as a prefilled autoinjector. Furthermore, in order not to jeopardise drug stability during shelf life, primary packaging components that come into contact with the drug must preferably be well known. Delivered dose accuracy and consistency is important, but in contrast to insulin pumps that require a very exact flow rate, the flow rate for a wearable bolus injector is less important. Thus, depending on the drug, it is less important if it takes, for example, five or seven minutes for the device to deliver the dose, as long as the injected volume is accurate.

Osmosis As A Driving Force

An actuator driven by an osmotic pump mechanism has many of the characteristics wanted for a low-cost device:

- It is inexpensive (energy is provided by means of salt and membranes)
- The energy is released slowly
- It has the ability to deliver a high pressure.

Further to these benefits, the excess water from the actuator can be used to provide a simple, compact and sophisticated hydraulic plunger pushing mechanism. However, the challenge of using osmosis as the driving force in an actuator lies in the concept being new for use in injectors and, thus, implementing the basic power concept in a practical, manufacturable solution.

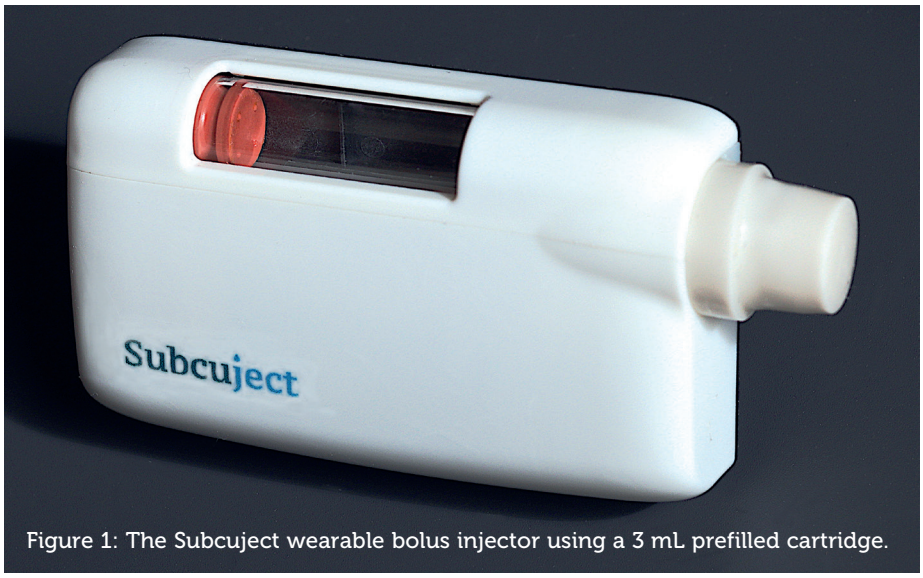

Figure 1: The Subcuject wearable bolus injector using a 3 mL prefilled cartridge.

Figure 2: The 3 mL Subcuject device attached to the body.

THE SUBCUJECT PRODUCT

The Subcuject wearable bolus injector is designed to be prefilled with drug from the manufacturer, of a small size and as simple to use as a prefilled autoinjector. Furthermore, it is designed to be low cost and to use standard primary packaging components (i.e. standard glass cartridge and a rubber stopper). The current moulded prototype shown in Figures 1 and 2 is based on a 3 mL cartridge.

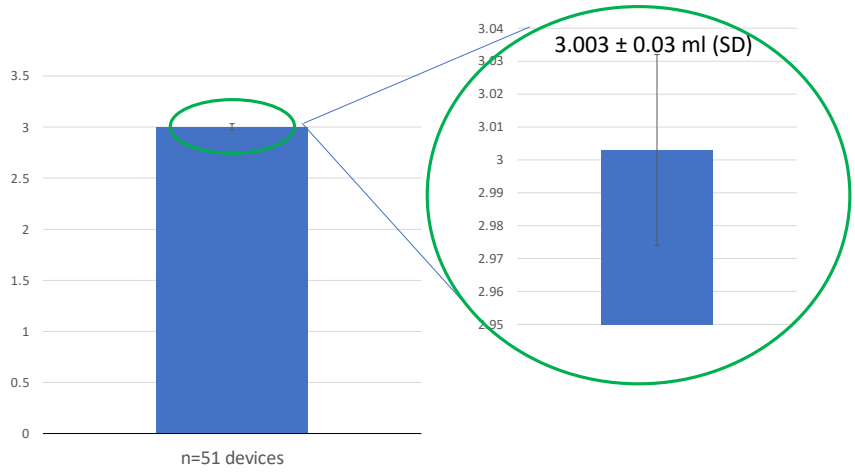

Figure 3: The Subcuject device's dose delivery consistency from a 3 mL cartridge.

Performance Consistency

The Subcuject product is currently in the late stage of concept development, and it has now been demonstrated that the product can be made repeatably as moulded single-use devices, with a very consistent delivered dose of 1% standard deviation over 3 mL (Figure 3).

The injection time is repeatable, and the injector can overcome high viscosities and high back pressures (Figure 4). The average injection time for 1 cP (water) is about four minutes, 50 cP takes five minutes and 100 cP takes about five and a half minutes.

> "The Subcuject product is currently in the late stage of concept development, and it has now been demonstrated that the product can be made repeatably as moulded single-use devices."

The time for injection against an extreme condition of 10 psi is about six minutes. These data demonstrate that the wearable injector can generate a high force and that high viscosity has limited impact on injection time.

The flow rate profile is likewise consistent during the injection. A typical flow profile of a 100 cP viscosity injection is shown in Figure 5.

As described, the results show that the base technology is powerful and consistent when implemented in a single-use device. All data on injection time discussed in this article were collected with the cartridge facing upwards, as when the device is attached to the abdomen in a standard-use position, but the dual membrane geometry used in the device ensures a similar injection time for all other possible positions. Tests with 1 cP were performed with a G30 needle and tests with higher viscosities use a G27 needle.

Outlook And Availability

The Subcuject wearable bolus injector will be ready for the first drug development combination programme in 2020, in partnership with one of the global top-tier contract development and manufacturing organisations.

The first commercial version is now being designed for a 5 mL glass cartridge.

ABOUT THE COMPANY

Subcuject develops an innovative and proprietary device platform for wearable bolus injection. The company is organised as a virtual organisation, working closely with external experts and specialist organisations. The management team and board of directors have decades of experience and a track record in medical devices, pharma and drug delivery. The company is located north of Copenhagen, Denmark and is privately held.

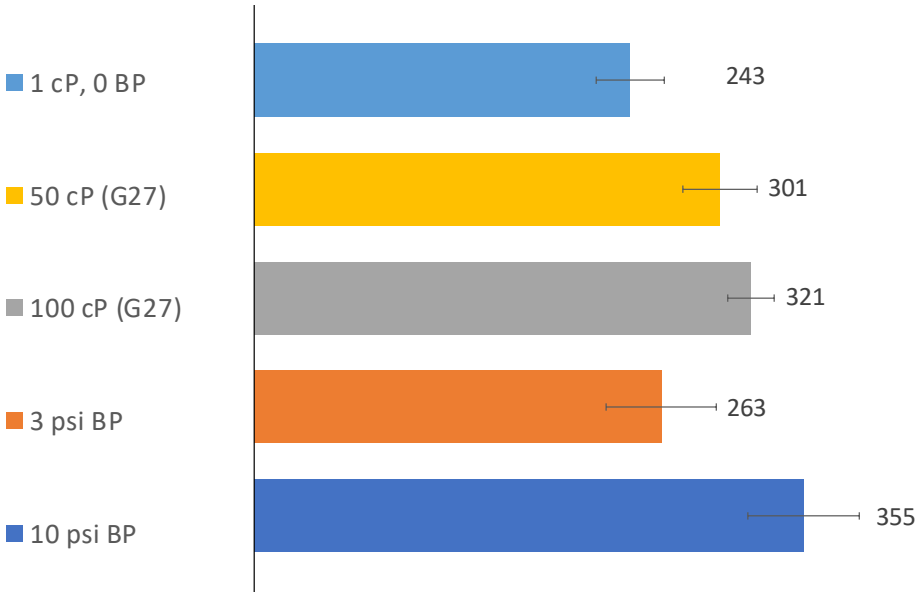

Figure 4: Total injection time (seconds) under various conditions using the Subcuject device with a 3 mL cartridge.

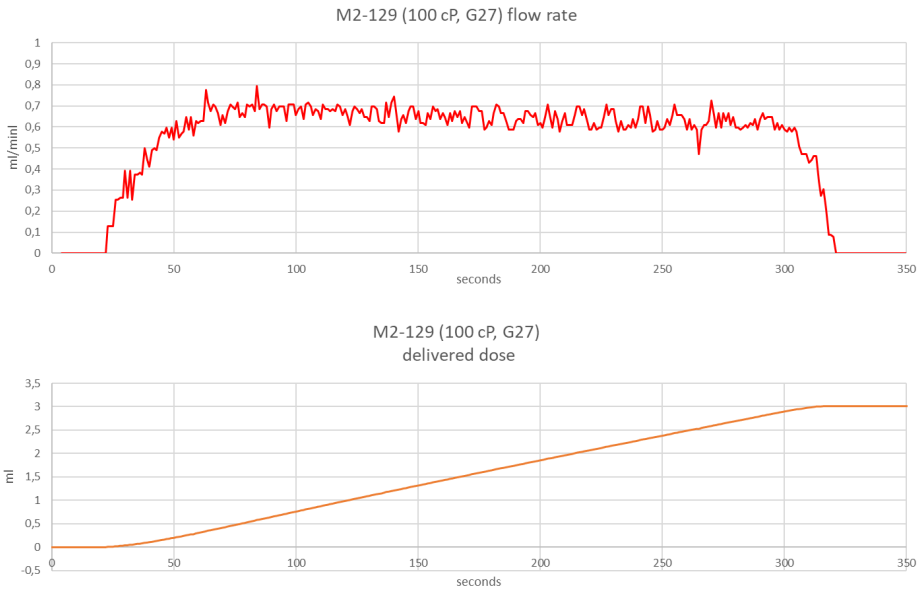

Figure 5: A typical flow rate profile of a 100 cP viscosity glycerol injection using the Subcuject device.

ABOUT THE AUTHORS

Jesper Roested holds an MSc in Medical Electronics and Physics and has 25 years of experience, most of which has been in business development and management roles in the life science industries. As part of his experience, Mr Roested spent seven years as a partner in a venture capital fund, specialising in medtech. Mr Roested has been CEO of Subcuject since 2018 and has been involved with the company since its formation in 2017.

Tomas Gundberg is an independent test and design engineer owner of the consultancy and workshop Fixit, based in Denmark. Mr Gundberg has been involved in the development of a large number of innovative medical devices with 20 years' experience in developing medical devices, of which about 12 years experience is in infusion sets and patch pumps. Mr Gundberg has been involved in the Subcuject project since 2017.

ON drugDELIVERY

2020/21 EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
September/ October 2020	Drug Delivery & Environmental Sustainability	PASSED
October 2020	Prefilled Syringes & Injection Devices	Sep 24, 2020
November 2020	Pulmonary & Nasal Drug Delivery	Oct 8, 2020
December 2020	Connecting Drug Delivery	Nov 5, 2020
January 2021	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Dec 3, 2020
January/ February 2021	Prefilled Syringes & Injection Devices	Dec 17, 2020
February 2021	Novel Oral Delivery Systems	Jan 7, 2021
March 2021	Ophthalmic Drug Delivery	Feb 4, 2021
April 2021	Pulmonary & Nasal Drug Delivery	Mar 4, 2021
May 2021	Delivering Injectables: Devices & Formulations	Apr 1, 2021
June 2021	Connecting Drug Delivery	May 6, 2021
July 2021	Novel Oral Delivery Systems	Jun 3, 2021
August 2021	Industrialising Drug Delivery	Jul 1, 2021
September 2021	Wearable Injectors	Aug 5, 2021
September/ October 2021	Drug Delivery & Environmental Sustainability	Aug 19, 2021
October 2021	Prefilled Syringes & Injection Devices	Sep 9, 2021
November 2021	Pulmonary & Nasal Drug Delivery	Oct 7, 2021
December 2021	Connecting Drug Delivery	Nov 5, 2021

EASING PATIENT EXPERIENCE WITH INNOVATIVE LARGE-VOLUME WEARABLES

In this article, Victoria Morgan, Director, Segment Marketing, Global Biologics, West Pharmaceutical Services, discusses the growing sector of wearable injectors, with a specific focus on West's own SmartDose® injector and the value of fill-finish services.

With an estimated 50% or more of the global population living with at least one chronic health condition – such as autoimmune disorders, cancer, cardiovascular disease, diabetes or neurological disorders – patients have an increasing need and desire for easy-to-use and reliable self-administered medications.

Pharmaceutical and medical device manufacturers are answering this call by rapidly developing new solutions designed to benefit the whole person holistically, rather than just their health condition. Modern healthcare seeks to provide patients with more individualised, flexible treatment options. In fact, in the context of the covid-19 pandemic, where many patients are wary about visiting doctors' offices and hospitals, some of these innovative solutions can help patients manage their conditions safely at home.

A GROWING HIGHER-VOLUME TREND

Higher-volume wearables are transforming the patient experience in an especially positive way. Large volume medicines have traditionally been infused or administered intravenously, due to the challenges of getting the required volume of drug into a patient's bloodstream. Historically, self-administration by a user has been unsuccessful for several reasons, including the inherent difficulty of holding a device in place for the required amount of time, the high viscosity of the drug(s) to be administered and the inability of subcutaneous tissues to absorb large drug volumes. Therefore, patients frequently had to travel to clinics and hospitals for treatment.

For patients, this state of affairs causes inconvenience and disruption to daily life, incurs transportation costs and acts as a constant reminder of their disease state, all of which results from the lack of a functional self-administered treatment. Thus, pharmaceutical and device manufacturers are driven to focus on designing cost-effective drug administration processes that prioritise a better patient experience.

The invention of wearable devices and technologies, for example, which degrade the hyaluronan in the subcutaneous space,

> "Advancements in technology have allowed for larger volumes to be administered subcutaneously, over a longer period, in a non-clinical setting by ensuring user requirements are at the heart of the patient experience."

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are upstream changes that have met with the downstream desire of patients to have more influence over their disease management.

BENEFITS OF BIOLOGICS

Advancements in technology have allowed for larger volumes to be administered subcutaneously, over a longer period, in a non-clinical setting by ensuring user requirements are at the heart of the patient experience. Pressures on drug formulation and packaging have been particularly relevant in the field of biologic drug administration, which utilises high volume, high viscosity formulations. The new biologics pipeline continues to grow, with a focus on lifecycle management and total cost reduction. The total number of drugs in the pipeline has grown 42% from 2016 to 2019, as has the number of injectables.[1]

Pipeline biologics molecules are often focused on narrowly targeted therapies and small patient populations with reduced side-effects and reduced dosing. Current trends see a consistent growth in approval of combination products with a compound annual growth rate of 13% from 2015 to 2019, according to IQVIA audited data.

With changes in delivery methods for patients targeted towards increasing ease-of-use and compliance, the shift from intravenous therapies to subcutaneous injections is rapidly expanding beyond the diabetes and auto-immune therapy spheres, into blood diseases, cardiology, oncology and other chronic conditions (Figure 1).

Along with new molecular entities, drug development companies are looking to reformulate existing commercial molecules into volumes suitable for a wearable. As shown in Figure 2, these companies are becoming more comfortable with bringing combination products to market. This increase in combination products means more opportunities for device innovation, benefitting pharmaceutical companies, patients and payers as follows:

- For the pharmaceutical company, drug delivery methods can be used to protect market share from biosimilar competition, such as with Neulasta® (pegfilgrastim) Onpro® (Amgen, Thousand Oaks, CA, US).
- For the patient, high-volume subcutaneous injections for chronic indications offer advantages such as less frequent injections, improved adherence and a home setting for a better patient experience.

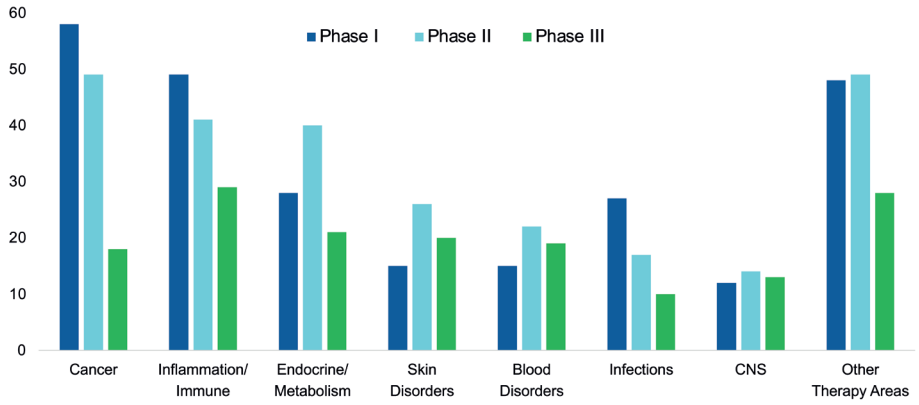

Figure 1: Number of new molecular entity subcutaneous biologics programmes in the clinic, sourced from PharmaCircle.

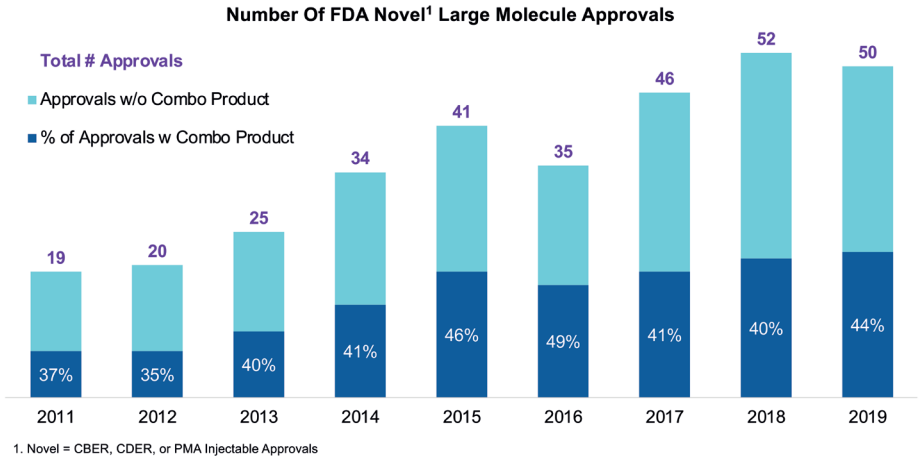

Figure 2: The increase in combination products means more opportunities for device innovation.

- For the clinic/payer, a move from intravenous to subcutaneous drug delivery offers savings including:
  - faster drug prep-time improves pharmacy efficiency[2]
  - fixed dosing reduces drug waste and medication error[3]
  - less set up reduces nurse's time.[2]

WEST'S SMARTDOSE® INJECTOR

West Pharmaceutical Services recognised these trends over a decade ago, and has been investing in wearable technologies since 2010. West's first offering was the wearable and programmable SmartDose® injector, which is a technology used by Amgen today in their Pushtronex® device (Figure 3). Amgen's Repatha® (evolocumab) was approved by the US FDA In 2016 for hyperlipidaemia in the Pushtronex® device. This became the first FDA-approved large-volume wearable for commercial use. Human factors testing showed the design, functionality, size and comfort were all favourable to the patient, whilst simultaneously allowing Amgen to differentiate their offering to the market.

Figure 3: West's SmartDose® 3.5 injector used by Amgen for their Pushtronex® system.

Figure 4: SmartDose® 10 injector.

"West's SmartDose® 3.5 injector revealed a patient need for higher volume, subcutaneous delivery with programmable features to suit the dosing regimen of the therapy. As a result, West expanded its development to a platform of devices, demonstrating the company's commitment to wearable technologies."

West's SmartDose® 3.5 injector revealed a patient need for higher volume, subcutaneous delivery with programmable features to suit the dosing regimen of the therapy. As a result, West expanded its development to a platform of devices, demonstrating the company's commitment to wearable technologies. scPharmaceuticals (Burlington, MA, US) announced its intent to go to market with West's 10mL SmartDose® 10 injector (Figure 4) for FUROSCIX®, a proprietary, subcutaneously delivered furosemide solution, for the treatment of worsening heart failure due to congestion.[4] West's SmartDose® wearable injector provides an outpatient alternative for the treatment. The FDA accepted scPharmaceutical's NDA resubmission of FUROSCIX® in July 2020.

Alexion (Boston, MA, US) has also announced its adoption of the SmartDose® injector for two blood disorder products. ULTOMRIS® (ravulizumab-cwvz) utilises the SmartDose® 3.5 injector to help facilitate at home self-administration for ease of use.[5] The SmartDose® platform helps to provide patients with confidence in their therapy and reduce and prevent the need for frequent visits to infusion centres.

With considerable market traction around the SmartDose® platform, it's clear to see the results from West's early recognition of the trend for larger volume delivery. The SmartDose® 10 injector leverages the success of the SmartDose® 3.5 injector with proven engineering and industrialisation on a larger scale. New features include:

- Up to 10 mL delivery
- Preprogramable delivery times from minutes to hours
- Formulation viscosities up to 100 cP
- Continuous or pulsatile delivery modes
- Training system (Figure 5)
- Filling pathway.

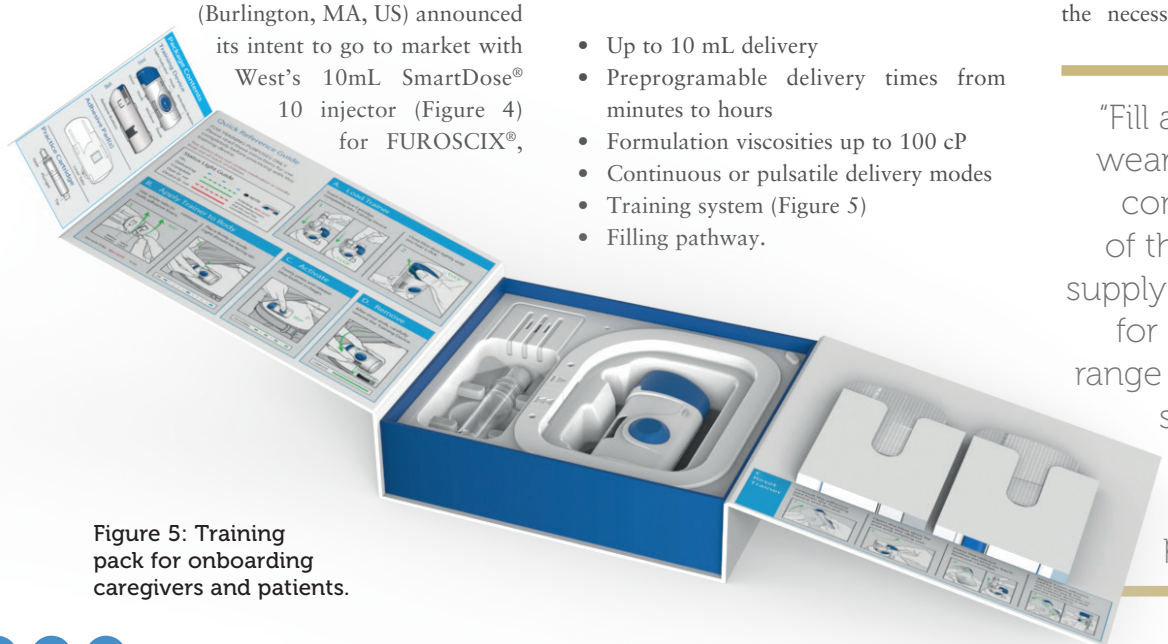

Figure 5: Training pack for onboarding caregivers and patients.

Extensive human factors testing has helped examine these usability and feature enhancements. The comprehensive design incorporated body mass index, age, health status and experience, and was arranged to test design usability, acceptability, comfort, whether the device addressed the patient needs and what was the monthly preference for administration. Study users selected the SmartDose® 10 injector as an acceptable treatment and rated it higher than all of the alternatives, including autoinjectors, visiting a clinic for intravenous injection or infusion, and even multiple doses with the lower volume SmartDose® 3.5 injector (Figure 6).

FILL-FINISH CONNECTS DEVELOPMENT AND DELIVERY

Fill and finish services for wearable containers are a complex yet critical part of the drug development supply chain. Requirements for fill and finish services range from small-scale fills, suitable to take to the clinic, through to commercial scale production volumes. Finding a partner who can support a drug developer's requirements in the right way, at the right time and without risk to the overall development timelines can be time consuming.

Recognising the need to strengthen the device offering and take a more collaborative, integrated approach to supporting a customer has been a key driver for West. When it's time to move an injectable drug product to clinical testing or commercialisation, drug developers need a partner who can provide an integrated solution that will streamline drug product development and provide the necessary expertise and partnerships

"Fill and finish services for wearable containers are a complex yet critical part of the drug development supply chain. Requirements for fill and finish services range from small-scale fills, suitable to take to the clinic, through to commercial scale production volumes."

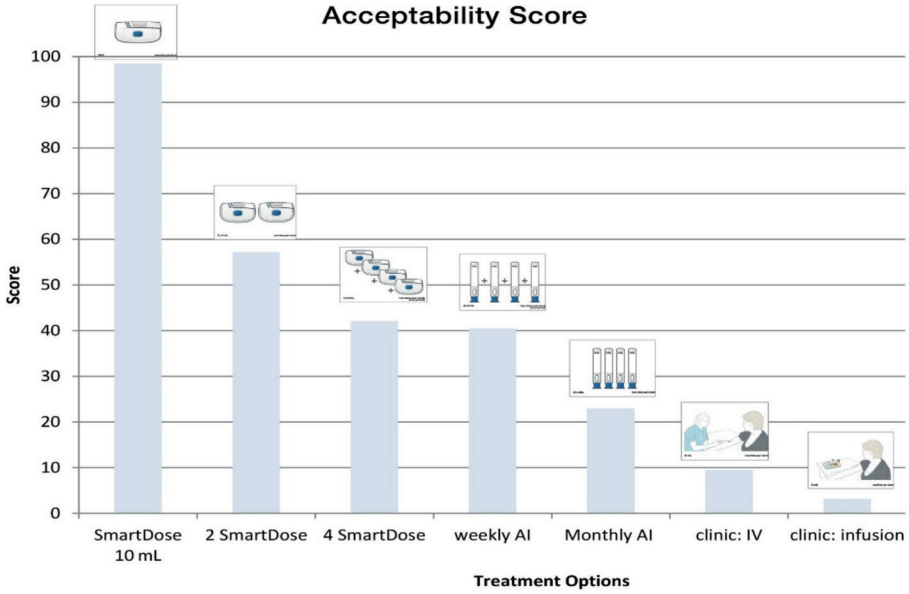

Figure 6: Human factors study results showing SmartDose® 10 injector is the preferred administration route.

to accelerate drug products to market. West is now able to offer in-house small-scale laboratory filling services to help customers with sample preparation for product testing through to product and process characterisation. West can support a drug development company with good manufacturing practice filling at established contract manufacturing organisations, or enable a customer's new fill-line or retrofits in-house.

To further strengthen the offering to customers, West partners with Swissfillon (Visp, Switzerland), a provider of aseptic fill and finish services to pharmaceutical and biotechnology companies. Swissfillon specialises in flexibility, quality and speed, and with expertise in complex biologic fill-finish services, from clinical through small-scale commercial opportunities. Swissfillon enables fill-finish for West's SmartDose® platform of wearable injectors, including the 10 mL cartridge.

Through this collaboration, it is anticipated that West will be able to deliver an integrated solution with filled Crystal Zenith® cartridges for the SmartDose® platform, which is expected to accelerate clinical development and enable customers to bring their innovative injectable drugs to market quickly. This collaboration is expected to offer customers a robust fill-finish manufacturing service.

West has seen many changes over the past decade whilst developing its device platform, enabling fill and finish capabilities and leveraging a wealth of expertise in componentry, devices, regulations and testing as an integrated solution to customers. The appetite for wearables is considerable and West will continue to grow and evolve to predict and respond to the trends to help ensure its customers are providing up-to-date and innovative options for patients.

ABOUT THE COMPANY

West Pharmaceutical Services is a manufacturer of packaging components and delivery systems for injectable drugs and healthcare products. Working by the side of the world's leading pharmaceutical, biotechnology, generic drug and medical device producers from concept to patient, West creates products that promote the efficiency, reliability and safety of the global pharmaceutical drug supply. Additionally, West provides a comprehensive Integrated Solutions programme that combines high-quality packaging and delivery systems with analytical testing, device manufacturing and assembly, and regulatory services to support customers throughout the drug development lifecycle.

West is headquartered in Exton, PA, US, and supports its customers from locations in North and South America, Europe, Asia and Australia. West's 2019 net sales of US$1.8 billion reflect the daily use of approximately 112 million of its components and devices, which are designed to improve the delivery of healthcare to patients around the world.

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ABOUT THE AUTHOR

Victoria Morgan, Director, Segment Marketing, Global Biologics, at West, has been in the pharmaceutical industry for more than 25 years. She has extensive experience across primary and secondary care and the area of injectable drug delivery products, including primary packaging and combination products for vial, prefilled syringe systems, cartridges and devices.

Throughout her tenure at West, Ms Morgan has served in various functions across sales and marketing. Ms Morgan has spent more than 17 years in global sales roles, followed by three years as Director of Segment Marketing, Biologics, at West, where she has responsibility for global biologics strategy development and implementation.

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