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SELFCARE SOLUTIONS

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

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possible. The following sections outline key development aspects of the YpsoDose platform, which is being industrialised for clinical and commercial use.

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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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

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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).

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



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

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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- Attach, inject and dispose for simple and ergonomic handling
- Clearly communicates via audio and visual signals before, during and after injection
- Sterile ready-to-fill cartridge and needle unit for easy drug filling and final assembly
- Unique electromechanical drive system for a range of viscosities and fill volumes



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