



# COMBINING INDIVIDUAL DESIGNS WITH THE BENEFITS OF A PROVEN PLATFORM PRODUCT

In this article, Orfeo Niedermann, Business Development Director, Ypsomed Delivery Systems, gives insights into the requirements on modern self-injection devices and explains how the advantages of a proven platform product – short timelines, low risk and attractive costs – can be combined with the implementation of an individual industrial design, providing differentiation or tailoring to a specific patient group.

With the large number of new biologics, and the surge in biosimilar product launches, the demand for devices for the subcutaneous self-injection of biopharmaceuticals continues to grow and develop. New devices focus on simpler self-injection procedures and improved patient adherence for auto injectors, pens and larger volume injectors.

As the number of devices reaching the market increases, pharmaceutical and

these objectives can be challenging for pharmaceutical companies and device manufacturers.

## REQUIREMENTS FOR SELF-INJECTION DEVICES

Simple and safe use are key requirements of modern self-injection devices. Ypsomed uses a human centred design approach to create new concepts for injection devices. During the development process, multiple rounds of formative human factors studies provide feedback to improve the concept to make the use of the device easier and to support the patient's adherence to the therapy.

Typically the patient prefers a device that is discrete and compact. It should require only a few operation steps, may have a shielded needle and offer convenient disposal. Furthermore,

the device may have to provide simple dose setting when needed and has to fulfil dose accuracy and other requirements from the applicable standards.

Testing of the final device in Phase III studies calls for quick availability of devices shortly after the decision has been made that a device shall be used for commercial launch. All of the above factors are important for the successful development and launch of the final combination product.

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biotech companies are looking to source state-of-the-art devices that are available quickly and at low risk for both clinical trials and commercial launch. A self-injection device should provide product differentiation through improved human factors and increased safety compared to vial-syringe and prefilled syringe product presentations. At the same time, pharma companies strive to differentiate their own self-injection device from devices used by competitors. Meeting



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Figure 1: YpsoMate® – the 2-step auto injector in the original square shape.

## LEVERAGING PLATFORM PRODUCTS

As an answer to these requirements, Ypsomed has built up comprehensive platform products, which allow faster and simpler development projects while minimising project risks and shortening time to market. To achieve this, Ypsomed has decoupled the development of new platform products from the customer project and thereby moved risk in-house to cover platform development and installation of manufacturing infrastructure. In short the benefits of starting a device project of a platform product are:

- Prototype devices available off-the-shelf for handling studies
- Reduced project risks by building device projects on proven technology
- Established patent position
- Devices quickly available for clinical trials
- Short and reliable commercial project timeline
- Reduced project cost and unit price.

A highly successful platform product in Ypsomed's portfolio is YpsoMate – the two-step auto injector based on a prefilled syringe (Figure 1). It serves patients with an easy and convenient two-step automatic injection.

The patient pulls off the cap to remove the sterile needle shield from the prefilled syringe and then pushes the auto injector onto the skin to trigger the injection. The operation is simple and safe and does not involve any additional button-activated steps. An additional activation button requires more user steps and is often inconvenient to perform for patient groups with limited dexterity. This was an important finding in Ypsomed's human-centred design process and a key reason for the success of two-step auto injectors.

The YpsoMate auto injector signals the start as well as the completion of the injection through clearly audible clicks. In parallel the patient can observe the injection progress in the large viewing window.



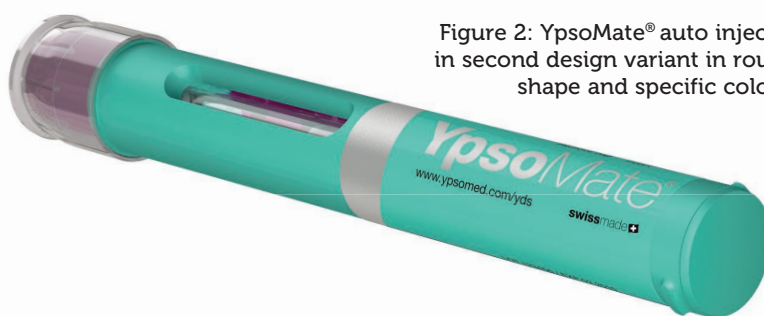
During the injection the needle remains hidden and is shielded after use to prevent needle stick injuries. All these features are built into a compact housing that fits nicely into the palm of the hand and is easy to dispose of.

## CUSTOMISATION IS KEY

A modern and successful self-injection device needs to be adapted to the selected primary container, to the formulation characteristics such as drug volume and viscosity and to the needle insertion depth as required for certain therapies. Ypsomed has therefore designed the YpsoMate auto injector to be compatible with all available 1 mL long syringes made of glass or COP and for a range of needle shields from all major suppliers whether rigid or flexible.

The YpsoMate platform product is also easily adapted to the drug product to meet specific fill levels and viscosities in conjunction with the selected needle gauge and needle penetration depth.

Figure 2: YpsoMate® auto injector in second design variant in round shape and specific colour.



## DIFFERENTIATION THROUGH INDIVIDUAL INDUSTRIAL DESIGNS

However, for certain products and indications there might be a strong demand for a unique product to differentiate from competitor products. Ypsomed offers YpsoMate in two standard designs (Figures 1 & 2) that are ergonomically proven and tested. In addition, different colours and colour combinations can be selected.

If specific patient groups, or demand for differentiation in a specific market, calls for a completely new outer shape Ypsomed offers the new device version, YpsoMate Design, that still relies on the proven YpsoMate technology. The technical concept of the outer shell structure of YpsoMate Design allows for more freedom to generate a unique, pleasing and ergonomically optimised shape. In addition to the possibility of designing free-form surfaces it is also possible to use different surface materials to improve the grip and to emphasise how to hold and use the device (Figure 3).



Figure 3: Example of YpsoMate® Design – a version of the proven YpsoMate® platform auto injector with a fully customisable, individual industrial design.



Figure 4: Flexible assembly line for fully customised YpsMate® auto injectors at one of Ypsomed's Swiss manufacturing sites.

In short, with YpsMate Design it is possible to manufacture a fully customised auto injector with specific technical characteristics including an individual outer shape on a fully automated manufacturing line. This solution provides the pharma company with a very specific and exclusive device while still leveraging all the advantages of the platform product.

#### EFFICIENT AND FLEXIBLE MANUFACTURING

To keep the timeline short and project upfront investment low, Ypsomed has invested in automated manufacturing capacity for the YpsMate platform product (Figure 4). This allows customers to access and source the device at a fraction of the overall cost compared to investing in

and generates two sub-assemblies that are nested to reduce packaging space before being arranged into trays and stacked for shipment to the final-assembly site. All standard housing versions as well as the YpsMate Design inner housing version are assembled on the same fully automated assembly line. The machine is interfaced with Ypsomed's SAP system and all parts entering the machine are traceable in the resulting sub-assemblies.

#### FLEXIBILITY & SUPPORT FOR DRUG & DEVICE FINAL ASSEMBLY

For the drug and device end assembly process, Ypsomed fully supports its pharma partners to help select the best possible logistics for their product and supply chain. To support the final device assembly step,

labelling and packaging of the final combination product.

When using YpsMate Design, the equipment is additionally configured to assemble the outer shells around the auto injector housing.

#### CONCLUSION

The demand for a specific and exclusive self-injection device is not incompatible with the clear need for easy to access proven technology. Based on a well thought out design, that considered a broad range of customisation during early development of the technical concept as well as during the parallel development of the manufacturing process, the YpsMate auto injector platform product can meet virtually all biopharmaceutical needs for a simple and attractive yet affordable self-injection device.

#### ABOUT YDS – YPSOMED DELIVERY SYSTEMS

Ypsomed is the leading independent developer and manufacturer of innovative auto injector and pen injector systems for self-administration. The customisable product platforms cover auto injectors for prefilled syringes in 1 mL and 2.25 mL format, disposable pens for 3 mL and 1.5 mL cartridges, re-usable pens that include automated injection mechanisms and easy-to-use injection devices for drugs in dual-chamber cartridges such as lyophilised drugs. Unique click-on needles and infusion sets complement the broad self-injection systems product portfolio. Ypsomed provides its partners excellent technological expertise and full regulatory support for the device relevant aspects of the registration process.

The injection systems are developed and manufactured 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 are regularly inspected by both pharma customers and regulatory agencies and supply devices for global markets including US, Europe, Japan, China and India. Ypsomed has more than 30 years of experience and well-established working relationships with numerous leading pharma and biotech companies.

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bespoke manufacturing infrastructure.

The fully automated line consists of four individual cells that are linked with a conveying system. The components, which are all moulded at the same site in Switzerland, as well as the special springs, are delivered into the machine with feeding systems. The assembly equipment inspects the parts inline

Ypsomed works with a select number of renowned assembly equipment manufacturers to prepare machine concepts for manual, semi-automatic and fully automatic equipment for different capacity needs. This allows the pharma company to pursue the appropriate final assembly strategy objectively in combination with the inspection,



YpsoMate®  
Design

# Go for your individual design.



swissmade 

## The 2-step autoinjector.

- Individual designs for different target patient groups
- Proven platform product for low risk and short time to market
- Push-on-skin release for most simple handling
- Clear confirmation “clicks” and large viewing window for optimal patient confidence and control

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