



CASE STUDY: IMPLEMENTATION OF A STATE-OF-THE-ART HIGH-VOLUME MANUFACTURING LINE FOR A DISPOSABLE PEN PLATFORM PRODUCT

In this overview, Tobias Nemeth, Business Development Manager, Ypsomed Delivery Systems, outlines the advantages of platform product development and manufacture and goes on to describe the implementation of the UnoPen™ high-volume manufacturing line, which is designed and developed to manufacture a range of customised pen versions.

INTRODUCTION

Over the last 30 years, the demand for pen injectors and more recently autoinjectors for the self-administration of therapeutic proteins and antibodies has grown significantly. This market demand has been mainly controlled and driven by global pharmaceutical companies willing to invest significant resources in the development and manufacture of new injection systems for their new biologic and chemical entities. As global demand continues to grow and pen and autoinjector technologies have matured, pharmaceutical companies at all levels are now looking to source state-of-the-art devices that are available quickly and at low risk for both clinical trials and commercial launch.

Platform products, like Ypsomed's UnoPen™ (Figure 1), disposable pen and Ypsomate® two-step autoinjector, support customers by providing fully developed state-

of-the-art injection systems that are customised to fit perfectly the properties of the drug and the customer-specific trade dress.

PLATFORMS MITIGATE RISKS

The main advantage of developing a product platform is to speed up time to market and to minimise risk for the customer during product development and the commercial life of the custom product. This is achieved by developing the platform to a level, which allows customisation within defined limits as a final step before the custom product is available for clinical and ultimately commercial supply.

Self-injection platform product development is built around experienced interdisciplinary teams working in key areas:

- Broad knowledge of the patent landscape and securing IP for the new platform allowing product launches in key markets.
- Human factors studies at the platform



Figure 1: The UnoPen™ disposable pen platform accepts 3 mL or 1.5 mL cartridges and is customised for use with insulin, GLP-1, hGH, FSH and PTH.



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Figure 2: UnoPen™ is delivered for final assembly in three different subassemblies: (1) pen cap, (2) cartridge holder and (3) dose mechanism.

level taking into account a broad range of patient populations and disease states. This underpins design input for further human factor studies performed on the final custom product.

- Development and industrialisation specialists working hand-in-hand from concept development to the final product encompassing key aspects such as technical design, material selection, friction forces and manufacturability. In the case of UnoPen™ special attention was paid to the development of a unique “active last dose stop” and also on “sound engineering” to provide an optimal audible and tactile patient experience during dose setting and correction.
- Final assembly expertise of the UnoPen™ subassemblies (Figure 2) together with a range of specialist suppliers to fully support customers building up final assembly capacity based on manual, semi-automated and/or fully automated lines.

Ultimately, one of the most important factors is to install manufacturing capacity for the new platform to allow customers to access the platform easily at a fraction of the



Figure 3: The UnoPen™ manufacturing line.

overall cost compared with bespoke manufacturing infrastructure. The manufacturing line must be capable of producing multiple customised design and technical versions. An individual design is important to accommodate customer requirements on human factors and trade dress. Technical modifications

with the highest accuracy and based on short changeover times between versions. New customer versions can be implemented quickly without significantly interrupting commercial manufacturing of already established products. The first installed line has an annual capacity of up to 20 million units. The overall

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ensure that the injection system is compatible with the dosing requirements and the filled volume of the primary packaging container.

THE UNOPEN™ MANUFACTURING LINE

The key specification requirement for the UnoPen™ assembly line was to be able to manufacture each customised pen version

infrastructure is available to extend this initial capacity significantly exploiting synergies between various processes.

The UnoPen™ manufacturing line (see Figure 3) not only comprises the necessary assembly steps but also the equally important inline checks and controls. The assembly stations are cam-controlled, while the work piece carrier is based on an electromagnetic system that



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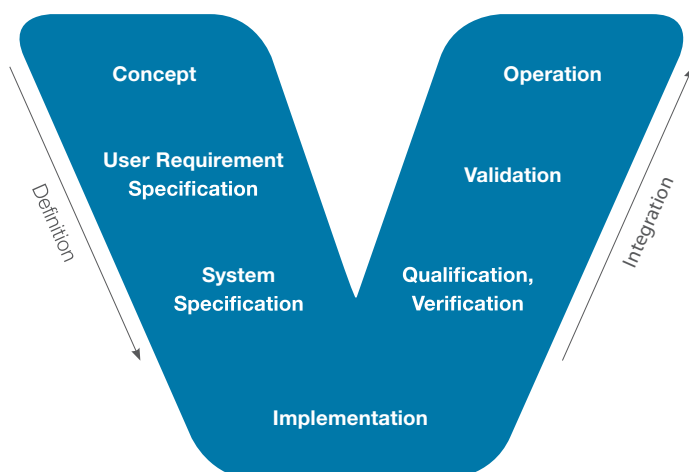


Figure 4: System engineering process V-model as used for the line set up for UnoPen™.

allows precise positioning at each work station and is almost maintenance-free. The line automatically controls the performance of each assembly station in real time. Functional checks of all assembled parts are performed in line. The line automatically withdraws parts or subassemblies for further quality checks or final customer samples. The machine is smoothly interfaced with Ypsomed's SAP system and all parts entering the machine are traceable in the finished product.

IMPLEMENTATION OF THE UNOPEN™ MANUFACTURING LINE

For line setup, Ypsomed followed a classic V-model (Figure 4). The concept phase focused on the overall manufacturing concept including injection moulding and supporting processes. For creating the User Requirement Specification it was important to consider all future technical and design variations in order to achieve the most

mance and reliability and which is located close to the Ypsomed manufacturing site for fast technical assistance and delivery of spare parts.

TEAMWORK

Ypsomed has been manufacturing hundreds of millions disposable pens for a number of customers since 1999 and currently has annual capacity based on customer-specific pens in excess of 90 million devices. For the UnoPen™, setting up a state-of-the-art manufacturing line with its demands in terms of quality, flexibility and reliability, requires profound know-how of all involved manufacturing processes and particularly close collaboration with the equipment supplier.

An Ypsomed industrialisation team accompanied the implementation work for the automated assembly line at the supplier's site. This not only made sure that all requirements were met, but also to train

installation could be realised in a short time and to move quickly on to site acceptance testing. Thanks to the close collaborative efforts during implementation and qualification / validation, commercial operation could be initiated seamlessly. The overall timeline from issuing the System Specification to final operation in less than two years is remarkable. The first customer has already received commercial product from the new line and other customer products are currently being implemented and validated. With more custom products in development and commercial customers likely to increase their forecast, Ypsomed is already reviewing when to invest in a second line.

CONCLUSION

The development and industrialisation of a new platform product like UnoPen™ require significant knowhow, investment and resources not only to develop the basic platform, including IP and human factors, but also to industrialise the platform on a large commercial scale that allows customers to source their product reliably from a state-of-the-art line with the highest level of automation.

YDS – YPSOMED DELIVERY SYSTEMS

Ypsomed is the largest independent developer and manufacturer of injection systems for self-administration. Our pens range from simple disposable pens to reusable pens with variable dosing and spring-assisted injection. We develop and manufacture autoinjectors for use with prefilled syringes as well as innovative injection devices for use with dual-chamber cartridges. Unique click-on pen needles complete our product portfolio.

All products are developed in Switzerland, where internal capabilities include R&D, tool-making, injection moulding, clean-room production and assembly facilities. Ypsomed provides not only marketing, regulatory and technological expertise but also manufacturing expertise according to the latest quality requirements, for both low and high-volume production. Ypsomed manufactures in US FDA-registered facilities, is inspected regularly and successfully by its customers and regulatory authorities (including FDA) and supplies devices to all leading markets including US, Europe and Japan.

Ypsomed has well established partnerships of many years with numerous leading pharmaceutical and biotech companies.

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flexible manufacturing approach. The line requires minimum human intervention during daily operation.

In addition to the technical specification and line flexibility it was also important to choose a supplier with an excellent reputation, a track record of building state-of-the-art lines with outstanding perfor-

Ypsomed's engineers and operators on the new line at an early stage. After successful factory acceptance testing the line was transferred to one of Ypsomed's manufacturing sites in Switzerland.

The Swiss site was prepared by installing all necessary connections based on a “plug-and-play” approach, thus ensuring that line

YDS


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