



FROM CUSTOMER NEEDS TO COMMERCIAL PRODUCTS: FAST & LOW-RISK CUSTOMISATION OF INNOVATIVE INJECTION SYSTEMS

In this article, Andreas Schneider, Business Development Manager, Ypsomed, highlights new emerging requirements of biopharma companies and describes how Ypsomed has established a range of innovative platform products, based on proven expertise and capabilities, and well-honed development and manufacturing processes, in order to meet its biopharma partners' and customers' needs fully and completely.

With the global increase in diabetes, the large number of new biologics, and the surge in biosimilar product launches, the importance of subcutaneous self-injection of biopharmaceuticals continues to grow. Modern therapy concepts that fulfil patients' and payers' needs for convenient, discreet, safe, compliant and cost-efficient drug administration further accelerate the trend towards self-injection.

Biopharmaceutical companies increasingly focus on self-injection devices as a mechanism for differentiating the drug product. As a result, manufacturers of innovative drug delivery systems have become

of injection systems to equip biopharmaceutical companies, in a flexible manner, with novel injection pens and auto-injectors customised to their individual needs.

Responding to these emerging requirements, Ypsomed has built up comprehensive platform products that each meet key customer needs yet are specifically designed to be modified into customer-specific products. The platform products enable flexible customisation while minimising project risks and shortening time to market. Ypsomed decouples the development of new platform products from the customer project and thereby moves risk in-house

to cover platform development and installation of manufacturing infrastructure (see Figure 1). Each customer project stems from an existing platform based on an established patent position and proven technology.

Driven by patient needs, market intelligence and new technology, the development of novel platform products also requires significant investments in manufacturing capacity.

key partners for the successful development and commercialisation of the final combination product. Increased pressure on healthcare product prices, increased complexity in drug formulation, and more stringent regulatory scrutiny require manufacturers

Ypsomed supports its partners not only by customising the injection systems to market demands, dosing needs, and to the primary container but also by incrementally expanding its installed manufacturing infrastructure to match customer capacity

"Manufacturers of innovative drug delivery systems have become key partners for the successful development and commercialisation of the final combination product"



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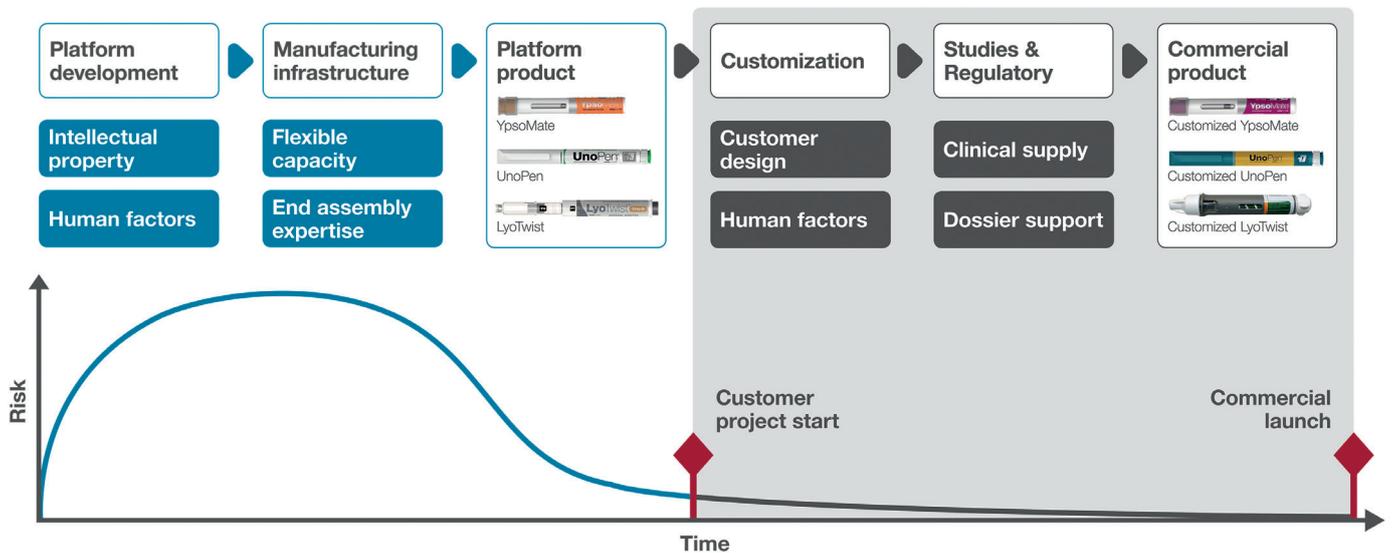


Figure 1: Ypsomed’s platform-based product strategy lowers risk and shortens timelines during customer projects.

requirements. Ypsomed today offers one of the broadest ranges of pen and auto-injector platforms (Figure 2) and supports its customers in selecting the ideal device for their specific application.

Consider the UnoPen (shown in Figure 2), Ypsomed’s variable and multi-dose disposable pen platform that offers key features such as intuitive dial and dose handling, audible feedback during dosing and delivery, or the last-dose stop functionality to ensure that the dialled dose cannot exceed the remaining volume in the cartridge. Customisation

to individual design, dosing, and cartridge requirements makes the UnoPen platform ideal for use across a range of hormone-based therapies including – but not limited to – insulin, glucagon-like peptide-1 (GLP-1), human growth hormones (hGH), follicle stimulating hormone (FSH), or parathyroid hormone (PTH).

Ypsomed’s platform products also include the growing auto-injector segment for pre-filled syringes. The YpsoMate (Figure 2) disposable auto-injector provides patients with an easy and convenient two-step auto-

matic injection. The patient first triggers the injection by pushing the auto-injector on to the skin. The device then signals completion of the injection through a clearly audible end-of-injection click and visual feedback in the large viewing window. The needle remains hidden during injection and is shielded after use.

The platform-based strategy for injection systems accelerates time to market and lowers project risk only if accompanied by appropriate capabilities. It is precisely the unique combination of the platform-based strategy and capabilities that

	Pens								Autoinjectors			
	ServoPen®	YpsoPen®	UnoPen™	UnoPen™ Fix	LyoTwist™ Trio	LyoTwist™ Trio S	LyoTwist™ Vario	LyoTwist™ Vario S	YpsoMate®	YpsoMate® Control	YpsoJect®	VarioJect™
Reusable	•	•										
Disposable			•	•	•	•	•	•		•	•	•
Automatic injection	•						•	•	•	•	•	
Multiple-dose	•	•	•	•								
Single-dose					•	•	•	•	•	•	•	•
Adjustable dose	•	•	•	•			•	•				•
Fixed dose			•	•	•	•			•	•	•	

Figure 2: Ypsomed’s range of pen and auto-injector platforms.

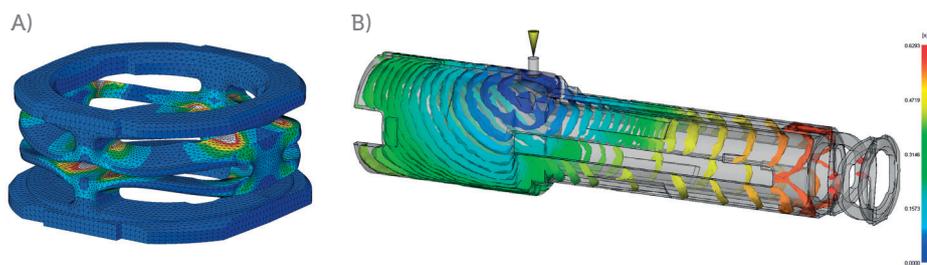


Figure 3: Computational modelling techniques used for development, evaluation, and testing of self-injection devices. The two examples are based on the mechanic holder, a key component of YpsoMate, the two-step auto-injector: (a) Finite Element Analysis of the mechanic holder front part, (b) Simulation of the flow characteristics after injection of the molten thermoplastic into the mould cavity.

enables Ypsomed to manage all processes during the development of innovative injection systems effectively – from early-stage innovation, clinical supply, and commercial launch, to customer support throughout the product lifecycle. Specifically, Ypsomed's ability to develop novel platform products and to supply tailored injection systems flexibly and efficiently for almost any customer need rests on four key capabilities:

- (1) Key expert functions centralised in one location in Switzerland
- (2) The consistent use of state-of-the-art development methods for device design and testing
- (3) Installed automated manufacturing capacities
- (4) Expertise as consultants in drug delivery and injection systems.

Centralised expert functions:

Ypsomed views the integration of specialised in-house expertise as an essential instrument for effectively adapting platform products to its customers' needs. Accounting for the uniqueness of each customer project, Ypsomed equips project

injection devices directly shapes Ypsomed's organisational set-up.

Throughout all customer project phases, such as customisation to individual design requirements, human factor studies, clinical supply, or regulatory filing, all competencies are centered at Ypsomed headquarters in Burgdorf, Switzerland. Co-location enables a richer and more efficient dialogue among experts, supports rapid learning processes across specialisations, and helps to establish as well as sustain effective risk management programmes. Tight cross-functional integration is essential for early-stage, in-house new product platform development as well as for the installation of manufacturing infrastructure. Ypsomed seamlessly integrates knowledge from market research (e.g. patient feedback, emerging user needs, or novel therapy concepts) with insights from design ideas, intellectual property and technical calculations.

State-of-the-art development methods:

To accelerate the development of new platforms and customisation of platform products while mitigating any technical risks, Ypsomed leverages a comprehensive toolbox for device design and testing.

finite element analysis is routinely applied to develop and evaluate functional designs of new device parts (see Figure 3a).

Generating a mathematical model that accurately reproduces material properties; finite element analysis helps generate the optimal design solution through repeatedly twisting and deforming the virtual prototype with the help of dedicated software. Other computational methods used for the investigation of manufacturing processes (see Figure 3b) further contribute to shortening turnaround times and lowering risk.

Similarly, in-house rapid prototyping, or prototype tooling, enable Ypsomed to prepare prototype parts and functional devices quickly, independent of the project stage. Rapid prototyping provides models in less than 24 hours for demonstrational purposes or initial functional evaluations. Despite the apparent technology-driven approach to the development of new devices, experts at Ypsomed integrate the abilities, preferences, and limitations of the device user in their design considerations following appropriate human factor studies.

Reflecting an essential information package required to work towards market authorisation, human factor (HF) studies minimise any use-related risks. Early formative HF studies, for instance, are accomplished to iteratively adapt the initial design of the device and refine the instructions for use. Constant involvement of end-users throughout new product development ensures that the final injection system avoids potential user-related errors.

Installed automated manufacturing capabilities:

New platform development requires timely investment in manual, semi-automated, and automated manufacturing capacities specifically designed for platform products. Strengthening its manufacturing sites in Switzerland, Ypsomed leverages already available technical expertise and continuously improves the manufacturing process. Ypsomed manufacturing facilities can be easily scaled to meet changing customer demand and account for future expansion. In addition, the facilities are able to manufacture different customer variants with unique industrial and technical designs with the appropriate level of automation.

For the UnoPen platform, Ypsomed has invested significant amounts in building up generic manufacturing capacity to meet initial customer demand. In so doing, Ypsomed pools investments in manufacturing infrastruc-

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teams with specialists from project management, product and process development, customer management, regulatory, risk management, quality assurance and control, purchasing, and complementary expertise beyond its organisational boundaries, such as industrial design and human factors research. The need for tight cross-functional integration in developing innovative

The technical experts employ a range of cutting-edge tools and technologies, such as finite element analysis, rapid prototyping, design for manufacture, mould flow analysis, and human factors engineering. During all stages of development these methods help shorten timelines, improve device performance, meet regulatory requirements and minimise any residual risk. For instance,

ture across customer projects and lowers the overall costs for customers to access a platform and develop their own commercial product.

Expertise as consultants in drug delivery and injection systems:

Ypsomed's depth of expertise as a consultant in drug delivery is highly valued by its customers. In particular, biotech and pharmaceutical companies working toward their first market introduction of an originator biologic or biosimilar may have little experience in evaluating drug delivery devices. Based on their unparalleled expertise as consultants, Ypsomed specialists have guided numerous customers through the design and development of innovative self-injection devices or the compilation and review of data required for product registration.

For instance, the US FDA and international regulatory bodies have increased requirements for combination product human factor studies. Ypsomed supports its customers with necessary know-how and device samples to conduct formative and comparative patient studies early on in the customisation process. Ypsomed serves as a single partner from customisation, to regulatory submis-

sions, to the launch of the final product and customer support during later stages of the product life cycle. As such, Ypsomed similarly guides its customers through drug and device end-assembly. For each device Ypsomed has detailed machine specifications for end-assembly available and reaches out to its network of dedicated machine partners with their ready-to-use automation concepts for low-, mid-, and high-volume capacity.

Ypsomed has moved beyond its traditional role as developer and manufacturer of injection devices, by facilitating collaboration outside its organisational boundaries from the full customer project up to final drug and device assembly.

The unique combination of a platform-based product strategy with the distinct set of organisational capabilities enables Ypsomed to support its customers throughout all stages of injection system development and supply as a single point of contact (see Figure 1).

ABOUT YDS - YPSOMED DELIVERY SYSTEMS

Ypsomed is the leading independent developer and manufacturer of innova-

tive pen and auto-injector systems for self-administration. Products and services at Ypsomed Delivery Systems centre on the customisation of injection systems, contract development and/or manufacturing, as well as drug and device end assembly. The product platform covers disposable pens for cartridges, re-usable pens that include spring-assisted injection mechanisms, single-dose auto-injectors for prefilled syringes, and reconstitution devices for lyophilised drugs in dual-chamber cartridges. Patented click-on pen needles complement the broad self-injection systems product portfolio.

The injection systems are developed and manufactured in Switzerland with strong in-house competencies covering product development, tool-making, injection moulding and assembly. All processes are run according to design control and cGMP guidelines with operational QA/QC experts on-site at each location. Ypsomed's FDA-registered manufacturing facilities are frequently inspected by both customers and regulatory agencies. Spanning more than 30 years, Ypsomed has well-established working relationships with leading biopharmaceutical companies.

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