

Title

Moving from Pre-Filled Syringe to Auto-Injector How to reduce timeline and risk for your combination product?

Abstract

Self-injection devices such as autoinjectors are becoming more important to facilitate injections and to differentiate biologics and other injectable drug products. Many pharma companies focus largely on their core competence of developing and marketing drug products and prepare initially a pre-filled syringe presentation. When decided to consider also an autoinjector combination product they are seeking solutions to implement a device without unknown risks and longer timelines.

The Webinar presentation gives insights into the drug characteristics that have an influence on determining the suitable autoinjector configuration. The concept of platform device products is explained as working with a proven autoinjector platform technology offers valuable benefits for pharma companies that want to avoid risks and timeline delays. Further the presentation gives an example of how such an autoinjector platform is tested and established and provides a complete list of design input specifications that need to be ready at the start of a device implementation project. Finally the drug and device end-assembly is explained and again possibilities to reduce risk and timeline are clarified.

Further additional options to upgrade a platform autoinjector into a connected, digital (IoT) device to allow the implementation of a therapy management system is introduced as well as a new option is announced to evolve autoinjectors into carbon free products to meet patient's future expectation for more sustainable products.

Author

Orfeo Niedermann
Business Development Director
Ypsomed Delivery Systems

Orfeo Niedermann has been with Ypsomed since 2005 working with pharma and biotech partners to develop and bring to market innovative self-injection systems. He studied mechanical engineering at the ETH Zurich (MSc ETH) and management in Berne (MBA BFH) and has worked in various positions in engineering, project management, sales and management of technical products, and for more than 15 years in the field of medical devices.

Portrait picture



Contact details

YPSOMED

Orfeo Niedermann

Brunnmattstrasse 6

CH-3401 Burgdorf

Switzerland

Phone: +41 34 424 39 47

E-mail: orfeo.niedermann@ypsomed.com

www.ypsomed.com

Company logo:



Company logo:



Company profile English:

Ypsomed is the leading independent developer and manufacturer of both innovative mechanical and connected autoinjector and pen injector systems for self-administration.

The customisable product platforms cover autoinjectors for pre-filled syringes in 1 mL and 2.25 mL format, ready-to-use pre-filled patch injectors and disposable pens for 1.5 & 3 mL cartridges. Pen needles, infusion sets and insulin pumps complement the broad self-injection systems portfolio.

Ypsomed provides its partners with a complete range of technical 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 molding and automated assembly. Ypsomed is ISO 13485 certified and all processes are run according to design control and cGMP guidelines. Devices are supplied to global markets incl. US, EU, Japan etc.

会社概要:

Ypsomed は、自己投与のための革新的かつ機械的なコネクティッドオートインジェクタおよびペンインジェクタシステムを開発・製造している大手独立系開発企業です。

カスタマイズ可能なプラットフォームは、プレフィルドシリンジ 1mL・2.25mL、ready-to-use プレフィルドパッチインジェクタ、1.5mL・3mL カートリッジ用の使い捨てペンタイプに対応可能です。加えて、ペンニードル、輸液セット、インスリンポンプと、幅広い自己投与システムのポートフォリオを提供しています。

Ypsomed はビジネスパートナーに対し、薬事申請においてデバイスに関わる幅広い技術的専門知識を提供し、全面的に薬事申請をサポートいたします。

投与システムは、コンセプト・製品開発から金型作製、射出成形、自動組立に及ぶ強力な自社の能力にて、本国スイスで開発、製造されています。Ypsomed は ISO 13485 の認証を取得しており、設計管理や cGMP ガイドラインに従って全てのプロセスを実行しています。Ypsomed 社製のデバイスはアメリカ、EU、日本などの世界市場に供給されています。

Extract of platform products overview:

