



YPSOMED AG - SELF CARE SOLUTIONS

Product approval in an environment that is subject to international regulation using ⁴PEP

The Ypsomed group is leading and independent in the development and production of injection systems for self-administered medication. With ⁴PEP, Ypsomed relies on the competency of ILC GmbH in the area of **Regulatory Affairs Management**. As proven diabetes specialists with more than 25 years experience, arisen from the well-known Disetronic, Ypsomed now offers insulin pumps and injections systems as well as pen needles for the treatment of diabetes, growth disorders, infertility and other therapeutic areas. Ypsomed is a **renowned leader in innovation and technology** and is thus a preferred partner of pharma and biotech companies in the area of self-medication.

*“With ⁴PEP Regulatory Affairs Management, we control our international approval processes safely and quickly. We were able to always represent our requirements **flexibly** with the solution from ILC. ILC consultants’ high process competency resulted in a **high quality implementation**.”*

Fernand Portenier,
Head of IT, Ypsomed AG

Company

- name: YPSOMED AG
- location: Burgdorf (CH), additional production sites and subsidiaries
- industry: medical technology
- products: injection systems for self-medication
- revenue: 379 m CHF (2020)
- employees: 1,816 worldwide
- www.ypsomed.com

Initial situation and challenge

- process oriented planning, processing and periodic renewal of the approval
- quality assurance and control at any site
- analysis and optimization of existing processes
- increase of legal safety of existing approvals

Solution

- secure management** of all documents relevant to the approval
- dossier management on the basis of checklists
- submission management: overview of the current status of the approval at the push of a button
- time management with reminder function

Customer benefits

- IT-supported, safe approval process
- transparency** concerning all approvals at the push of a button
- traceability by third parties
- efficient** and structured working method

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