

Media Release

Ypsomed enhances self-injection device platforms with integrated human factors services

Burgdorf, 05.10.2023, 7 a.m. – Ypsomed announces new Human Factors (HF) services for its pharmaceutical partners to reinforce its position as a leading developer and manufacturer of self-injection solutions. By enhancing its device platform offering with integrated end-to-end HF services, Ypsomed is championing a comprehensive service approach to combination product development that de-risks regulatory approval and expedites time-to-market for its partners. To do so, Ypsomed has entered into a strategic partnership with Interface Analysis Associates LLC (IAA), a leading HF service provider with long-standing expertise in supporting the pharmaceutical industry along the full combination product development journey.

Ever-increasing regulatory requirements, the complexity of integrated project planning, and difficulties in accessing cutting-edge expertise have underscored the critical role of HF in navigating the complex path of combination drug product development to successful regulatory approval. In response to these challenges, Ypsomed unveils end-to-end HF services to its pharmaceutical partners that reshape the trajectory of device turn-key HF services. Ypsomed is fortifying its commitment to efficient and successful deployment of its devices on the market, providing our clients with a one-stop solution.

The integrated HF services enable Ypsomed to offer its pharma and biotech customers the necessary expertise to minimize regulatory risks and speed up the device customization process, ultimately creating a positive effect on time to market. Specifically, Ypsomed offers HF services, such as formative evaluation, custom designed Instructions for Use, FDA approval strategy assistance, and summative human factors validation testing. Ulrike Bauer, Chief Business Officer YDS, explains: "The optimal interplay between HF and device development streamlines projects, enabling pharmaceutical partners to embark on device development with increased agility and efficiency."

To secure long-term access to cutting-edge HF capabilities and testing facilities, Ypsomed cooperates with IAA, which is led by Dr. Anthony D. Andre, a renowned expert in HF for medical devices and drug delivery combination products. The alliance with IAA enables Ypsomed to access specialized resources with an outstanding track record supporting the HF journey throughout combination product development, including effective FDA correspondence and successful HF dossier submission.

As Ypsomed unveils this milestone, it remains steadfast in its commitment to innovation and service transformation to amplify the potential of and simplify access to cutting-edge device platforms. "This partnership with IAA is the next step towards providing comprehensive solutions that address all facets of our pharmaceutical partners' combination product development needs", comments Ulrike Bauer.

Human Factors

Human factors focuses on the interactions between people and devices. For medical devices, the most important goal of the human factors process is to minimize use-related hazards and risks and then confirm that these efforts were successful and users can use the device safely and effectively. This is a necessary and critical component of a combination product and medical device submission.

About Ypsomed

Ypsomed is the leading developer and manufacturer of injection and infusion systems for self-medication and a renowned diabetes specialist with over 35 years of experience. As a leader in innovation and technology, it is a preferred partner of pharmaceutical and biotech companies for pens, autoinjectors and pump systems for administering liquid medications. Ypsomed presents and markets its product portfolios under the umbrella brands mylife Diabetescare directly to patients or via pharmacies and hospitals as well as under YDS Ypsomed Delivery Systems in business-to-business operations with pharmaceutical companies. The company is headquartered in Burgdorf, Switzerland, and has a global network of production facilities, subsidiaries and distribution partners employing a staff of over 2,000 employees worldwide.

About Interface Analysis Associates

Interface Analysis Associates LLC (IAA) is one of the world's premier Human Factors consultancies, in business since 1993. IAA specializes in the application of human factors science to the design, evaluation, testing, validation and regulatory support for all types of combination drug products. IAA's unique blend of extensive experience, personal attention, and turn-key services helps ensure that their client's products are usable, safe, satisfying, desirable and ultimately approvable. IAA's services include IFU and labeling development, device design optimization, expert human factors evaluations, generative, comparative, formative and validation testing, and regulatory strategy support.

Contact

Susanne Koehler, Public Relations, Ypsomed Holding AG
+41 34 424 47 32, susanne.koehler@ypsomed.com

Ypsomed Holding AG

Brunnmattstrasse 6
3401 Burgdorf / Switzerland
www.ypsomed.com