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Measurement technology for drugs: why process monitoring is essential

 Ivers-Lee

YPSOMED
SELF CARE SOLUTIONS



The auto-injector from Ypsomed is one of two platforms that are combined with drugs and reliably finished at Ivers-Lee – thanks to the integrated process monitoring solution from Kistler.



The 9323AA press force sensor from Kistler monitors both the drug insertion step and the reintegration of the actuator module into the auto-injector.

Ivers-Lee takes advantage of Kistler's integrated force-displacement monitoring in its assembly lines for drug-device combination products. Sensors and process monitoring systems operate in the final stage of the assembly process for auto-injectors and pen systems, ensuring that these self-medication products meet the highest quality standards.

Thanks to advances in the medtech and pharmaceutical industries, patients can now manage the treatment of many conditions themselves. One example is diabetes, a disease whose incidence is on the rise amid growing affluence – and not infrequently the result of a combination of an unbalanced diet and too little exercise. Self-management of this and many other conditions is more comfortable for the patient, and saves trips to the doctor; however, this requires totally reliable, user-friendly devices of the highest quality.

Nevertheless, many hurdles need to be overcome before a suitable product is approved for commercial marketing. Above all, clinical studies must be carried out to verify the efficacy of the drug; such studies are very costly and extremely time consuming. To streamline the obligatory processes and reduce time-to-market for their products, many pharmaceutical manufacturers invite Ivers-Lee to come on board. This Swiss company can look back on a long tradition of leadership in its field. It has a workforce of 100 at its headquarters in Burgdorf near Bern and another 10 employees at its site in Lörrach, Germany.

Integrated force measurement technology ensures 100 percent testing

Dr. Peter Schüpbach, CEO of Ivers-Lee, says: "We help our customers in the pharmaceutical sector to develop a

market-ready product. To achieve this, we draw on our lengthy experience of providing solutions for production, packing and labeling." Ivers-Lee's operations focus mainly on blister packaging and stickpacks as well as assembly of combination products. Preparation of these combined drug-device kits involves assembling, packing and labeling a suitable device for administering medication together with a drug container (syringe, glass vial, etc.). Patients can then use these kits to manage their own treatment. "Our assembly department is particularly successful in connection with clinical studies. As a development partner for pharmaceutical companies, we offer an efficient platform that enables them to bring their combination products to market without having to build up their own in-house production."

Ivers-Lee is also a partner for two platform products marketed by Ypsomed: an auto-injector and a pen system. Like Ivers-Lee, Ypsomed is based in Burgdorf near Bern, so lines of communication are short and collaboration is close. Reto Maffioli, Senior Engineer at Ypsomed, explains the benefits of this partnership: "As a manufacturer specializing solely in

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Reto Maffioli, Ypsomed AG

medtech devices, we don't have our own pharma license. That's why we offer our customers the option of having the final assembly process undertaken at Ivers-Lee – they can call on a wealth of experience in the field and of course have the relevant authorizations. At the same time, we offer recommendations on the final assembly process of our products – in other words, how best to combine them with drug containers. Ivers-Lee works with industrialized machines that operate according to our tried and tested specifications." For the assembly process, Ivers-Lee uses semi-automatic systems built by a German specialized machine manufacturer – and these systems are also equipped with integrated force-displacement monitoring solutions from Kistler. This technology ensures 100 percent testing of critical assembly steps to guarantee the quality of the final product.

High process reliability and transparency save time and costs

Exactly what happens in this type of machine? As Project Leader and Operations Manager at Ivers-Lee, Simon Balasso is principally responsible for the entire process. He explains: "First of all, the actuator module must be removed from the auto-injector supplied by Ypsomed. The syringe can then be integrated with our client's drug; the next step sees the actuator module replaced, ensuring it engages securely. The last step in the process consists of packing and labeling." Both processes – inserting the syringe with the drug and reinserting the actuator module – are force-displacement monitored. The machine is equipped with the 9323AA press force sensor to capture the small forces involved, as well as the maXYmos process monitoring system by Kistler.

"The force-displacement monitoring solution from Kistler is of huge benefit to us. First, this technology makes it easier to obtain approval for the machine, which saves time and costs," Balasso explains. "Another factor is that customer syringes are sometimes outside of tolerances. There is then a high risk of greater forces occurring, and the scrap rate increases. Given the high cost of the drugs, it is of course essential to avoid that happening under any circumstances." Tolerances as tight as ± 0.5 mm demand high levels of precision, and each individual step must be documented in detail – especially if any deviations from the target process occur.

Calibration: efficient service directly from the manufacturer

Calibrating sensors is another important requirement that applies to medtech and pharmaceutical environments in particular. Regular verification of measuring equipment is the only way to guarantee that measured forces truly reflect reality so that pharmaceutical products are manufactured flawlessly. Balasso

reports: "When I was planning some essential recalibration work, I initially contacted the special-purpose machine manufacturer, who in turn referred me to Kistler. That's how I came into contact with their measurement technology experts for the first time. I'm extremely satisfied with our working relationship – I was quickly provided with assistance; the service technician was already familiar with the machine so he could perform the recalibration procedure efficiently."

Kistler's in-depth knowledge of the industry is a key factor here. In recent years, the company has collaborated intensively with businesses operating in the medtech and pharmaceutical industries to gain a precise understanding of their needs and requirements. The new ML version of the maXYmos TL process monitoring system is one result of these activities; it offers an FDA-compliant user management system and makes process validation even simpler than before thanks to predefined routines.

Close collaboration with the medtech sector and pharmaceutical industry

"The whole venture – from providing the machines and implementing the processes to completing the first customer project at Ivers-Lee – took about six to eight months," Balasso continues. "Thanks to the time that both we and Ypsomed invested, we now have an ideal platform that can efficiently meet varying customer requirements for product development." The trend is towards extremely high-quality, high-end products that are often elaborately packaged to give the patient a sense of confidence."

Reto Maffioli adds: "Time-to-market is often the decisive factor nowadays, and this is where force-displacement monitoring from Kistler gives us the critical edge. It also helps to ensure process capability and guarantees the quality of the final product. And it offers another huge benefit: the analysis of force-displacement curves gives me a solid basis of data – the basis I need for discussions with customers throughout the world. That often simplifies and accelerates process assessment and decision-making procedures because it's clear that everybody is talking the same language." This will also apply to future app-controlled "smart" systems for patients to administer their medication. These systems will do much more than ensuring that the device is operated correctly; they will also allow patients to use the stored data as the basis for clear, responsible answers to doctors and health insurers – so they will be able to continuously improve their self-medication or adapt it to new circumstances.



During final assembly of an auto-injector at Ivers-Lee – monitored by Kistler systems – the drive unit is removed, the prefilled syringe is inserted and the drive unit is then replaced.

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