Haselmeier GmbH uses TEAMED, a flexible system platform for medical and pharmaceutical products, to realize an efficient manufacturing process for hormone injector pens. This assembly solution from teamtechnik, with integrated functional test technology enables the cost-effective production of high-precision pens.
Because they are simple and safe to use, the demand for injection devices has grown. Haselmeier has developed an innovative pen injector system for the self-injection of a hormone preparation. It is made entirely from plastic and is ideal for treatment periods of 3 to 6 months. Each injection pen contains a very precise dosing mechanism, which prevents incorrect injections and inadvertent loss of medication. They are configured for the highest accuracy," explains Matthias Meissner, CEO of Stuttgart-based Haselmeier GmbH. "As a leading developer and manufacturer of injection systems, we have found an option which allows pharmaceutical companies to offer complex pens for short-term therapies at an acceptable price."

Using Modular Systems

This was no easy task. As a rule, it is not typically economic to produce small batches, as the costs of automatically producing an injection system are dependent on the size of the batch. Medical technology has become increasingly focused on disposable solutions in recent years and many system producers are now geared towards mass production, with volumes of at least 10 million units per year. "For those using conventional engineering solutions, there is a considerable cost challenge if unit volumes fall below 10 million pens, says Reiner Zeidler, who manages medical technology sales at teamtechnik Maschinen und Anlagen GmbH. The Freiberg-based company develops highly flexible production solutions based on modular systems enabling manufacturers of medical technology to quickly and economically adapt to changes in their markets. teamtechnik’s approach allows for the cost-effective production of even relatively small unit volumes.
Integrated, 100% End-of-Line Testing

When Haselmeier initially approached assembly system suppliers in 2009, their pen injector was still very much under development. Mattias Meissner recalls that this, as well as the medium-sized volumes, made it difficult to find a partner: “The risk inherent in developing a production system for a product whose design would continue to evolve as the system was being realized was too high for most.” Haselmeier required more than a reliable and economical assembly solution: the company also needed the injector pens to undergo 100% end-of-line testing of function and ease of movement – to be integrated within the production system. “I have to admit that this was not a standard job,” says Reiner Zeidler from teamtechnik. “However, our TEAMED system platform is designed to provide a highly flexible and extendable linear system for assembly and testing applications. We can satisfy virtually all of our customers’ requirements for medical technology solutions with TEAMED, including the considerable challenges that Haselmeier presented to us.” Sophisticated process technology and 100% end-of-line testing can be integrated into the TEAMED platform, which has been developed specifically to meet the needs of medical devices, diagnostics and pharmaceutical products. TEAMED enables production which is compliant with global guidelines and monitoring systems such as cGMP, FDA and CE and is certified to Class 6 clean room specifications. A key feature is that TEAMED incorporates processes from clinical Phase I and Phase II, continuing these through into series production – thus verifying critical processes at the earliest stages and providing reassurance for commercial scale manufacturing from the outset. TEAMED-based systems can be quickly adjusted to accommodate increasing production volumes, resulting in minimal downtime and disruption during scale-up.

“teamtechnik’s engineering expertise in medical device production technology meant that we were able to provide a proven process for testing the pen’s dose setting mechanism at the Newton-millimetre (N) level, offering an accurate and reliable solution for Haselmeier’s application,” explains Volker Patz, project supervisor at teamtechnik. Once the pens have been fully assembled, TEAMED’S integrated testing system checks that each unit’s dosing mechanism is working accurately by drawing it up and the pressing it down. The torque applied when drawing up can be determined to an accuracy of 0.001 N, whilst ejection force is measured to within 0.01 N.
About Haselmeier GmbH:
Haselmeier is a leading developer and manufacturer of pens and self-injection systems. The products have highly specific functions, designs and technologies and are sold throughout the world by leading pharmaceutical and biotech companies.

Feeding of Loose Dials

teamtechnik further optimized Haselmeier’s production system with a tailored solution for feeding loose dials. Laser engraving of the pen’s dosing dial is a delicate process, carried-out in a TEAMED satellite, away from the main production line. Just before the component is assembled, the tiny, yet clearly defined lettering for the scale is applied onto a fragile surface. Each dial is then checked thoroughly with a camera system before being screwed into the pen. Feeding the blank dials in a loose batch means we can avoid the need for the additional costs a tray solution. Volker Patz estimates that the additional purchase of disposable trays “would have resulted in a significant increase in production costs.”

The production system is now running and the pen injector product has been successfully launched into the market. So successfully, in fact, that Haselmeier is now considering increasing production from a 2-shift, 5-day week basis to 3 shifts over 350 days per year. “This will not present any problem for the TEAMED system,” says Reiner Zeidler. “It is designed to allow output to be scaled, facilitating continuous operation.”

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