CASE STUDY

Alere Technologies GmbH

An Innovative System Solution for a New POC Product

Monitoring Test Goes Into Series Production

The PIMA CD4 POC test for monitoring the progress of HIV infections developed by Alere Technologies GmbH is a unique diagnostic tool. With the complex assembly solution supplied by the teamtechnik Group, this specialist in fast diagnostic tests was able to move from manual assembly of samples to reliable series production on schedule.

team technik
PRODUCTION TECHNOLOGY

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Irfan Kavak
Medical Technology Sales for the teamtechnik Group

As their name indicates, point-of-care (POC) tests are conducted out and evaluated wherever a patient is receiving care, avoiding the need for laboratory testing. They quickly provide accurate information about the patient's state of health and help to improve the care he or she receives.

Modular assembly line from teamtechnik to assemble PIMA CD4 cartridges for Alere Technologies GmbH

Removal of the window with integrated camera to monitor the position

"We designed the PIMA CD4 test so that medical personnel with no previous specific knowledge of laboratory diagnostics could use it to regularly monitor HIV infections," explains Mattias Kreling, Director of Operations at Alere Technologies GmbH in Jena. The test is truly innovative and puts Alere, which has already made a name for itself in the area of instant diagnostic testing, in a unique position in the market. In less than 20 minutes, the test delivers a reliable result in the form of the current number of CD4 cells in the blood, an indication of the status of the immune system in someone infected by HIV. "Until now, there has been nothing comparable for this particular application," reports Mr Kreling. After Alere launched the test to global acclaim in 2010, it sought a partner to make the step from manual assembly to automatic production; a system specialist who could quickly and reliably develop and supply a solution to deliver an annual volume in the millions.

Experience in Automation for Innovative Products

Alere found such a partner in teamtechnik. "It was our modular TEAMED system platform that brought Alere to us; it piqued their interest because with TEAMED, we can develop a solution for almost any requirement for a medical device production system," says Irfan Kavak from the Medical Technology Sales team at teamtechnik Group. Alere was also persuaded by teamtechnik because the company was familiar with, indeed understood perfectly, the sophisticated processes that the project demanded. "We realize manufacturing processes as system technology," explains Irfan Kavak. "We bring many years of engineering experience to bear, have a comprehensive database of processes at our disposal and take the TEAMED system platform as the basis for our solution."
TEAMED has been specifically developed to meet the challenges associated with the assembly of medical and diagnostic devices, and of phar-

maceutical production systems. TEAMED facilitates the integration of sophisticated processes up to 100% end-of-line testing. It enables production compliant with global guidelines and monitoring systems such as cGMP, FDA and CE, and is certified to Class 6 clean room specifications. Of particular importance is the fact that TEAMED incorporates processes from prototype production directly into series production, thus verifying critical processes at the earliest possible stage, providing reassurance for future series production from the outset. Drawing upon teamtechnik's comprehensive library of processes, the TEAMED platform solution optimizes assembly times and reduces time to delivery.

Camera system, spotting, plasma treatment

Workpiece carrier with labeled component

Target Values Achieved in the Ramp-Up Phase

The TEAMED solution which teamtechnik has developed for Alere operates on a 3-second cycle with an output of 20 cartridges per minute, currently producing three million in a year. This volume can be easily increased if demand for the product rises. "We are assuming that annual production volumes will be in the tens of millions in the long term," says Matthias Kreling.

Matthias Kreling, Director of Operations at Alere Technologies GmbH

"We are completely satisfied with the design of the system and score the realization of the processes we asked for as 'very good'."

The conveyor system conveys 21 workpiece carriers through the system in a 100 mm pitch. One process is undertaken out at each station, followed by an interim test. The machine is fed manually with plastic components in trays and a tray-handling mechanism unstacks and separates the components, feeding them straight into the workpiece carrier in the chain. The sequence of steps at the processing stations includes labeling, laser marking the base component, plasma-jet surface treatment, cell suspension dosing, drying, fitting of a window, laser welding and finally testing. Even two months before the scheduled end of the ramp-up phase, the system reached an overall efficiency level of 70% and availability of 90%. "We are completely satisfied with the design of the system and score the realization of the processes we asked for as 'very good'", confirms Matthias Kreling.

"As yet, there is nothing comparable for this particular application."

**Matthias Kreling,
Director of Operations at Alere Technologies GmbH**

Aiming for the Same Goal

"All in all, the individual processes are not unusual," says Gerd-Uwe Seidel, who was responsible for managing the project for teamtechnik. "However, with a system that is will be producing something that has never been on the market before, the real challenge is how best to combine these processes. We had the edge over the competition because we can provide all the required elements, (from the standard platform to the actual processes), from a single source, and we could give assurances that it would all interface perfectly." Anyone planning a system for a new product always faces the same critical challenge: how to integrate all the stages required into a workable concept so that the end result is a perfect product manufactured economically in the appropriate quantities. Matthias Kreling believes that a company wishing to position itself as a strong automation partner in medical technology must possess three core competencies: technological expertise; an approach to cost management that takes account of the stringent regulations imposed by the authorities; and a willingness to communicate openly. "The latter might sound obvious, but it isn't always practised. Many system projects of similar complexity fail because the partners in the project have no common language. That's what makes teamtechnik a good partner."

About Alere Technologies GmbH:

Cologne-based Alere supports and supplies doctors and patients with easy-to-use instant diagnostic tests, a broad portfolio of diagnostic aids for clinics and laboratories and other healthcare services.

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The teamtechnik Group

Based in Freiberg, Germany, teamtechnik has been making intelligent and reliable automation solutions for the medical and solar technology and automotive sectors for over 35 years. With their focus on assembly and testing, the systems are distinguished by their modular and standardized process-oriented structure. teamtechnik is considered an international leader in highly flexible automation technology. The senior management team has set a sales target of € 145 million for the current business year. The company employs 800 people around the world. The majority of staff are engineers and highly qualified specialists. The teamtechnik Group has production sites in Germany, Poland, China and the USA.