



PROFITABLE AUTOMATION FOR DEVICE ASSEMBLY & FUNCTIONAL TESTING VIA STANDARDISED PLATFORMS

In this article, Reiner Zeidler, Sales Manager, Medical Systems, teamtechnik Group, outlines how the company's modular TEAMED production system meets industry's need for new solutions in this area – from early development applications right through to commercial-scale manufacture.

There is increasing demand for new solutions to automate the manufacturing of medical products from early-stage clinical trials through to a successful, high-volume production programme. Teamtechnik Group is a leading supplier in the development and implementation of turnkey production systems for medical devices.

THE TEAMED PLATFORM

With its TEAMED platform, teamtechnik offers a scalable linear production system for both automated assembly and

functional testing of devices (Figure 1). TEAMED is a multi-purpose automation platform, specifically developed to address the particular challenges associated with the assembly of medical devices and designed to meet the needs of pharmaceutical production systems.

The TEAMED platform enables the integration of sophisticated assembly processes (Figure 2) with up to 100% end-of-line testing. It also facilitates production that is compliant with international standards such as cGMP, US FDA and CE – and is certified to Class 6 Clean Room specifications.

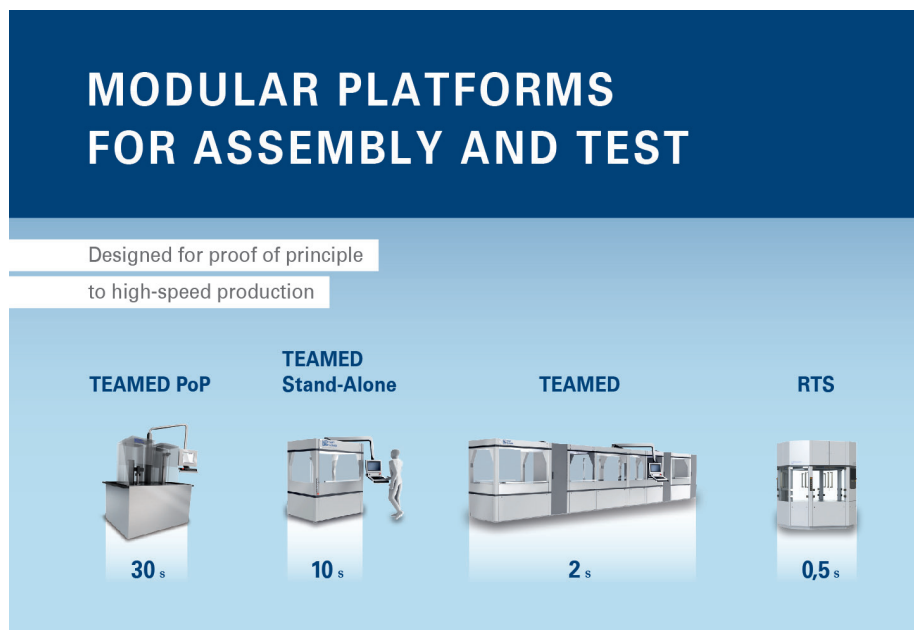


Figure 1: Modular platforms for assembly and function test.



Mr Reiner Zeidler
 Sales Manager, Medical Systems
 T: +49 (0) 7141 7003 179
 E: reiner.zeidler@teamtechnik.com

teamtechnik Group
 Planckstraße 40
 D-71691 Freiberg am Neckar
 Germany

www.teamtechnik.com

“To ensure that customers have access to relevant expertise during post-installation and ramp-up phases of their projects, teamtechnik provides resident engineers – based locally and available on-site – during this critical phase of a programme”

The TEAMED platform has been developed to cater for proof-of-principle applications as well as for high-speed industrialisation and enables the incorporation of processes which have been utilised for prototype production, directly into series manufacturing. This means that critical process steps are verified at the earliest possible stage, providing reassurance for future commercial-scale production from the outset of a programme. For example, Figures 3-5 show steps in the assembly of an injection device.

Drawing upon teamtechnik’s comprehensive library of processes and its engi-



Figure 2: Assembly system at TEAMED platform.



Figure 3: Testing and positioning the shell of an injector device.



Figure 4: Laser engraving the injector’s dial.



Figure 5: Testing and inserting the injector’s dial.

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neering expertise, the TEAMED solution optimises assembly processes and reduces time to commercialisation for new products.

A typical cycle of a development project and commercialisation for a new injectable device, utilising the TEAMED platform, is described below.

“TEAMED POP” FOR PROTOTYPE PRODUCTION

Phase I Clinical Trials

Injectable device assembly involves many complicated processes, which must either be monitored in-process, or results verified after the process. Ideally, in order to minimise time to market, a device design and assembly process would be completely defined from the outset of Phase I. For reasons of cost, risk and design evolution, this ideal is often not achievable and teamtechnik’s TEAMED PoP (proof-of-principle) platform provides a solution for such a challenge.

Incorporating both automated and manual elements, TEAMED PoP offers the ability to perform and monitor critical assembly processes with automatic solutions at a very early stage in a project, whether or not a device design has been fully defined at that point. Able to accommodate up to five process operators working at the machine, it is often the case that a customer will engage with teamtechnik and utilise TEAMED PoP, whilst a device is still in development.

“TEAMED STAND-ALONE” FOR SMALL-VOLUME PRODUCTION

Phase III Clinical Trials

Providing continuity from the Phase I experience utilising TEAMED PoP, the same process units can then be integrated into a TEAMED Stand-Alone machine for small-volume production to support Phase III clinical trials.

TEAMED Stand-Alone is a semi-automated assembly line with process materials

fed by operators, and with process stations being linked by a carrier transport system. The carrier features have the same design as in the corresponding TEAMED PoP machine, although typically incorporating additional nests for manually pre-loaded parts. Although most of the assembly operations will be performed automatically, the refined process stations are based on similar technologies to those on the precursor TEAMED PoP system.

“TEAMED” FOR INDUSTRIALISATION

Commercial Scale

For high-volume, commercial-scale production, teamtechnik provides a fully-automated TEAMED line with all device components being delivered by bowl feeders or palletising systems. The carrier design is ideally based on the same concept as used for the earlier TEAMED PoP and TEAMED Stand-Alone machines.

A number of critical processes – such as dosing, gluing or welding (ultrasonic or laser) – will typically have been refined and validated with the TEAMED PoP and TEAMED Stand-Alone systems, and are continued through in the design of the high-volume manufacturing line. The simple replication of validated processes can significantly reduce time to market for a new device, thereby improving return on investment. This benefit can be realised due the modular design of the TEAMED system, using individually customised processes and a machine concept which combines the flexibility and operational efficiency of pre-validated servo-actuated motions and cam-driven units.

“RTS” CAM-DRIVEN PLATFORM FOR HIGH-SPEED PRODUCTION

Drawing on the considerable experience and expertise of teamtechnik’s Pfuderer division, RTS is the company’s high-speed

automation platform. Typically operating at up to 120 cycles per minute, RTS offers a cam-driven ring transfer system, providing between eight and 32 individual stations, and is designed for processes which require the highest outputs.

MARKET LEADERS TRUST IN TEAMTECHNIK

Customers rightly expect robust, reliable and cost-effective production systems for their medical device products. Providing the foundation for long-lasting customer relationships, teamtechnik’s engineers are well-versed in the design and building of process technologies which offer sophisticated assembly and functional testing for a wide range of production applications.

ABOUT TEAMTECHNIK GROUP

Based in Freiberg, Germany, teamtechnik Group is an international leader in highly flexible automation technology and has been providing intelligent and reliable automation solutions for medical, pharmaceutical, diagnostic and other industries for several decades.

With 850 employees throughout the world, and annual revenues of more than €150 million (£120 million), teamtechnik supports customers from its bases in Germany, Poland, France, China, Korea and the US.

To ensure that customers have access to relevant expertise during post-installation and ramp-up phases of their projects, teamtechnik provides resident engineers – based locally and available on-site – during this critical phase of a programme. Through its global service network, teamtechnik also ensures that production equipment is available around the clock, providing customers with dedicated service team contacts, each with comprehensive knowledge of a particular customer’s manufacturing system.

FOR YOUR DEVICE. FOR YOUR SUCCESS.

Customers comments: „Outstanding performance“



Proven production systems

- Assembly and functional test
- Excellent product and process expertise
- From start-up to high-speed
- Solutions for proof of principle and prototype production

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