

PROFITABLE ASSEMBLY AUTOMATION THROUGH USE OF STANDARDISED MACHINE PLATFORMS

Here, Reiner Zeidler, Sales Manager, Medical Systems, teamtechnik Group, describes the company's modular TEAMED production system, and how it meets the inhaler device industry's needs – from early development applications right through to commercial-scale manufacture.

There is increasing demand for new solutions to automate the manufacturing of inhaler devices from Phase I clinical trials through to a successful high-volume pro-

(Figure 2) with up to 100% end-of-line testing. It also facilitates production which is compliant with global standards – such as cGMP, US FDA and CE – and is certified to

Class 6 Clean Room specifications. The TEAMED platform incorporates processes from prototype production directly into series manufacturing, thus verifying critical process steps at the earliest possible stage, providing reassurance for future series production from the outset.

The TEAMED platform has been developed for proof of principle applications as well as for high-speed industrialisation.

duction program. Teamtechnik Group is a leading player in the development and implementation of turnkey production systems for medical devices, offering a wide range of machine platforms.

Drawing upon teamtechnik's comprehensive library of processes, the TEAMED solution optimises assembly processes and reduces time to commercialisation for new products.

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

WHY USE MACHINE PLATFORMS?

With its TEAMED platform system (Figure 1), teamtechnik offers a scalable linear production system, consisting of proven standard modules which are then tailored specifically for each customer. Using such tested modules, the engineering required is much reduced and so are, therefore, machine delivery times.

The TEAMED platform enables the integration of sophisticated assembly processes

"TEAMED POP" FOR PROTOTYPE PRODUCTION

Phase I Clinical Trials

Assembly of injection devices involves many complicated processes, which must either be monitored in-process, or results must be verified after the process. In an ideal scenario, in



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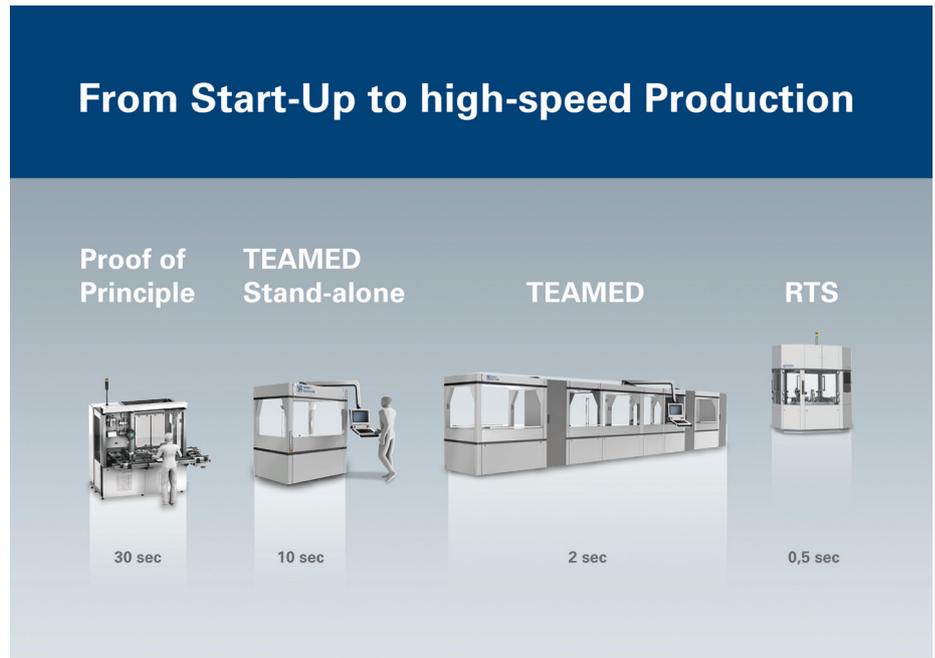


Figure 1: Modular platforms for assembly and functional testing.

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 not generally possible 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, while a device is still under development.



Figure 2: Assembly system at TEAMED platform.

“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, while a device is still under development”



Figure 3: Blister coiling.



Figure 4: teamtechnik's cam driven machine, RTS.

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 trials.

TEAMED Stand-Alone is a semi-automated assembly line with process materials being 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" PLATFORM 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, blister coiling (Figure 3) or welding (ultrasonic or laser) – will typically have been refined and validated with the TEAMED PoP and TEAMED Stand-Alone



Figure 5: teamtechnik provides resident engineers, based locally and available onsite, during post-installation and ramp-up phase.

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 by 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

teamtechnik's cam driven machine "RTS" (Figure 4) represents the company's high-speed automation platform. Typically operating at up to 120 cycles per minute, RTS offers a ring transfer system, providing between eight and 32 individual stations, and is designed for processes which require higher outputs.

well-versed in the design and building of process technologies which offer sophisticated assembly and functional testing for a wide range of production applications.

GLOBAL SERVICE CAPABILITY

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

With 900 employees throughout the world, generating annual revenues of over €150 million (£108 million), teamtechnik supports customers from sites in Germany, Poland, France, China, Korea and the US.

To ensure customers have access to relevant expertise during the post-installation and ramp-up phase of their projects, teamtechnik also provides resident engineers - based locally and available on-site

"The simple replication of validated processes can significantly reduce time to market for a new device, thereby improving return on investment"

MARKET LEADERS TRUST 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

- during this critical phase of a program (Figure 5). 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.

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