The Future of Aseptic Manufacturing

An interview with Marcel Weizel, Business Development Manager at Bausch+Ströbel

With GENEX, a new generation of robotic systems is transforming pharmaceutical production. The implementation of fully automated processes is establishing new standards in product and operator safety, operational flexibility and cost efficiency. In this interview, Marcel Weizel, an industry expert explains how these innovations will reshape cleanroom manufacturing and why Annex 1 plays a decisive role.

Robot-assisted cleanroom production has been central to pharmaceutical manufacturing for some time. How does the new GENEX system go beyond traditional automation?

Marcel Weizel: GENEX represents a fundamental shift. While robots have long been used for handling packaging materials, GENEX extends their role to critical tasks such as automated product path installation, bio- and surface-monitoring and even troubleshooting. These functions, which previously required manual glove interventions, are now performed fully automatically. This not only increases safety and quality but also reduces cost per unit, making advanced therapies more accessible to patients.

Why is this development so important for today's pharmaceutical industry?

Marcel Weizel: The industry is moving toward smaller and more flexible batch sizes. Large-scale systems have historically facilitated widespread availability of drugs such as insulin. Today's challenge lies in the ongoing development of specialised therapies, including orphan drugs and cell and gene therapies, which are manufactured in smaller quantities. GENEX is designed specifically for this environment. Its modular design allows manufacturers to adapt process chains to individual requirements while ensuring rapid and compliant setup changes.

You mentioned bio- and surface-monitoring as well as troubleshooting. What makes these capabilities unique?

Marcel Weizel: Automated bio- and surface-monitoring is a major leap. By utilising pre-programmed robotic movements, we ensure a level of reproducibility that surpasses manual interventions, while upholding the highest standards of sterility assurance. This is consistent with the regulatory requirements outlined in Annex 1, specifically chapter 2.1 i) and 9.22, which state that technologies such as robotic systems should be used to reduce contamination risks. Additionally, aseptic operations should be monitored through a combination of methods without negatively affecting grade A airflow. Troubleshooting is equally important. GENEX is capable of autonomously identifying and resolving problems, such as a stopper jam. These capabilities reduce the likelihood of product loss and introduce significant improvements to aseptic manufacturing processes.

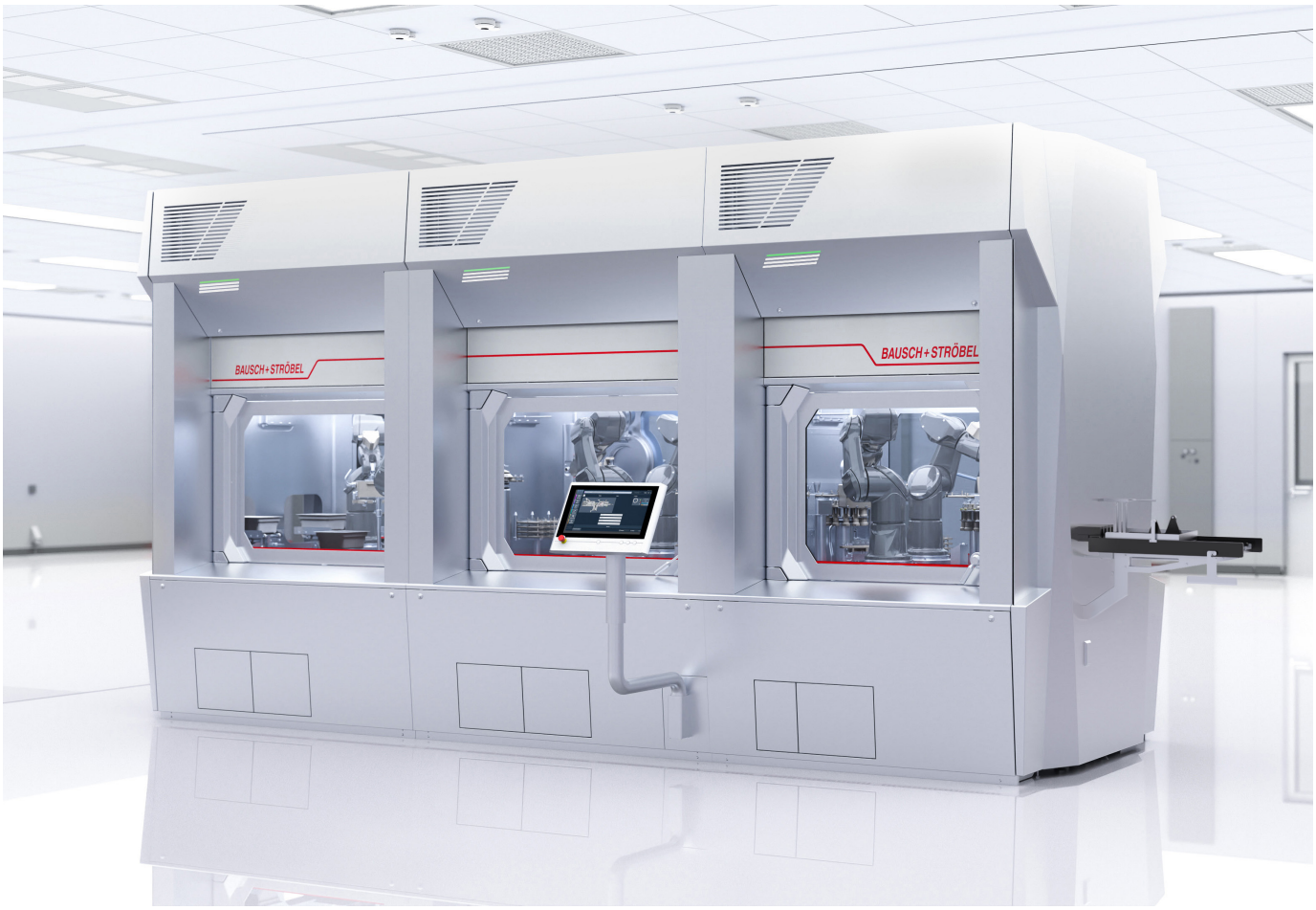
How does GENEX support long-term flexibility for manufacturers?

Marcel Weizel: Scalability is a key element. A line can be expanded or replicated to create parallel production setups. This also enables what we call "matrix production," where modules can be flexibly rearranged to match specific process needs. In case of a malfunction, production can simply be redirected, reducing the risk of batch loss. Looking ahead, we expect robotic systems to play a larger role not only inside the isolator but also outside, for loading, supplying spare parts, and transporting finished batches.

How do you work with pharmaceutical companies in developing these solutions?

Marcel Weizel: We see ourselves as solution providers rather than just equipment

Detailed illustrations showing the biomonitoring process sequence

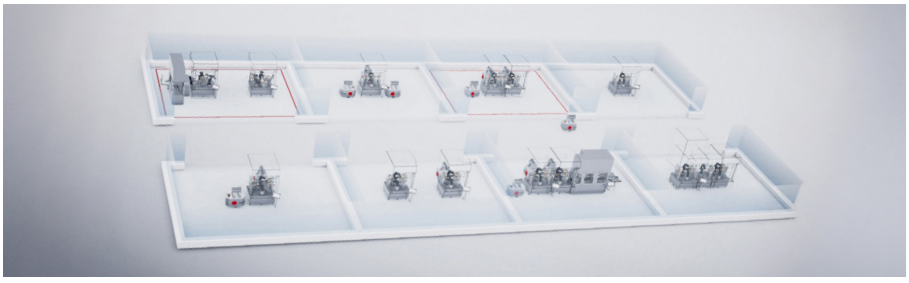


Until now, cleanroom robots have been used primarily for handling, supplying, and transporting packaging materials. More complex tasks – such as biomonitoring the production environment – were once thought impossible, but with GENEX, they are now a reality.

suppliers. That means working closely with customers to implement technologies that deliver measurable benefits. It also means supporting them over the entire life cycle of the system, from initial planning to operation and service. A comprehensive service portfolio is considered a fundamental component of the GENEX solution rather than an additional feature.

Regulations such as Annex 1 are shaping these technologies. What is your perspective?

Marcel Weizel: Annex 1 recognises the benefits of robotic systems in enhancing product protection against potential sources of endotoxins or pyrogens, particulate matter and microbial contamination, including those introduced by operators. Utilising a Robotic Gloveless Isolator such as Genex safeguards operators from exposure to highly potent substances, enhances process reliability and product quality and ultimately reduces the risk of contamination. This trend is reinforced by regulations; for example, Section 8.9 of Annex 1 recommends the implementation of robotics to eliminate direct human critical interventions within grade A environments. As equipment suppliers, we are committed to advancing aseptic processing toward fully gloveless operation spaces, drawing inspiration from best practices in semiconductor manufacturing, where robotic wafer-handling has been standard since the 2000s.



A look ahead: Matrix production made possible with GENEX.

General Overview

GENEX offers exceptional flexibility, adapting to the specific needs and conditions of pharmaceutical manufacturers. The line is built on a modular system, allowing individual process chains to be configured based on specific needs.

We will gladly provide you with further information on request.

Marcel Weizel

Marcel Weizel is Business Development Manager at Bausch+Ströbel, a manufacturer of pharmaceutical filling and packaging systems, where he is, among other things, an expert in the use of robot technology. He will be speaking about precisely this topic at CPHI in Frankfurt. The title of his presentation is: "Unlocking the Future of Aseptic Filling with GENEX – Robotic. Gloveless. Annex 1 Compliant."