

Big Strides in Small Batch Aseptic Processing

Growing demand for small batch processing poses new challenges for the life sciences sector. Adapting to variances while maintaining quality, efficiency and adherence to aseptic processing requirements is more complex than ever. Advanced Aseptic Processing (AAP) systems, enabled by robotics and other advanced technologies, offer inventive solutions. The GENiSYS® R aseptic small batch filling and closing machine from Automated Systems of Tacoma (AST) is a prime example.

AST is a U.S.-based pharmaceutical machine manufacturer specialising in advanced aseptic filling equipment and packaging machines, and a pioneer in the use of robotics in the fill/finish industry. Its relationship with Stäubli goes back more than two decades. In 2010 AST chose Stäubli to develop a multi-format robotic filling machine – the first ever capable of processing different types of container formats on a single machine.

The GENiSYS® R, launched in 2018, represents another noteworthy innovation. This flexible modular system automates aseptic filling and closing of ready-to-use vials, syringes and cartridges in strict accordance with cGMP requirements. It can be integrated with isolator-barrier or RABS technologies to maintain required aseptic conditions in tightly controlled ISO 7 and ISO 5 environments.

The GENiSYS® R is optimised for small batch filling, with a focus on dosing precision and high yield, and uses robotics to achieve 100% in-process control (IPC). This makes it ideal for clinical and commercial applications in drug manufacturing, compounding, cell and gene therapy development, personalised medicine, cytotoxic drug processing and other areas.

The IPC provides real-time fill weight feedback and control, which can be used to identify issues early on, ensuring quality, minimising waste, and maximising product yield. Electronic batch record (EBR) software records key production data that can be

used to create 21 CFR Part 11-compliant batch reports.

The combination of modular design and advanced robotics allow the GENiSYS® R to be configured to meet different process requirements and containers without the cost or extra time associated with customisation. Operators can program recipes specific to container formats and drug products, as well as precise robot movements and pump settings, using the intuitive human-machine interface (HMI), ASTView®. This can include fine-tuning needle fill depth and speed to prevent bubbling, or exact positioning in a given space to mitigate air disturbance, for example – with minimal downtime during changes.

The system’s modular design also provides flexibility with regard to the degree of automation desired: Bag and tub opening can be manual, semi-automated, or fully automated, while filling and vial sealing are always fully automated.

The Role of Stäubli Robots: Sterility, Quality and Safety Assured

For pharmaceutical and biotech labs tasked with processing complex small batches, there can be no compromises when it comes to precision, flexibility, reliability, IPC, and protection from contamination. Thus Stäubli’s six-axis TX2-40 and TX2-60 Stericlean robots, which excel in meeting these requirements, are integral to the GENiSYS® R. They are entrusted with a variety of delicate and repetitive yet critical tasks that could otherwise put product quality, the operator or the end user at risk.

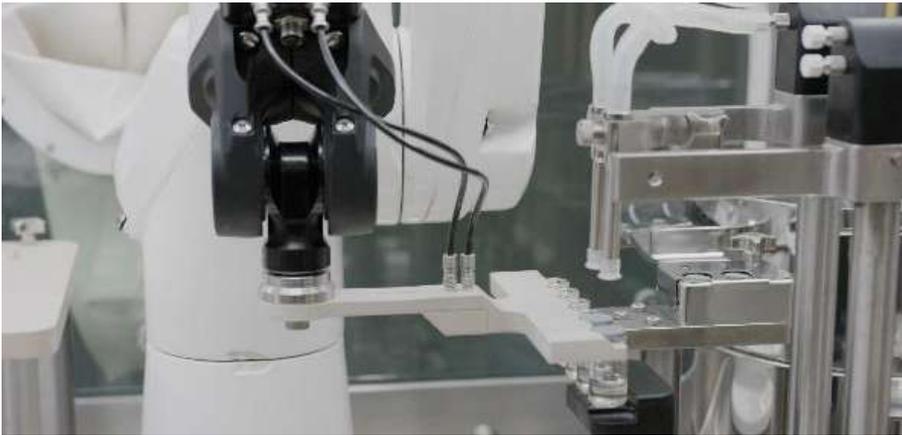
In addition to its past experience with Stäubli, AST had a variety of reasons for choosing Stericlean robots for the GENiSYS® R. As CEO Joe Hoff explained, “We needed robots that are reliable over a long period of time, extremely precise, and completely sterile, and the Stericlean line is designed for exactly that.”

Stäubli’s Stericlean range is suitable for GMP grade A and grade B tasks, and known for high performance in aseptic and sterile conditions. Extremely low particulate generation and VHP-resistant design enable the robots to reach cleanliness level ISO 5. They feature a fully enclosed IP65 arm with IP67 wrist, as well as an entirely smooth surface free of retention areas and coated with a high-resistance surface treatment. The arm is also equipped with specialised lip seals, and cables run through the arm and out vertically through the base. Critical parts are made of stainless steel.

A spherical work envelope and compact size make TX2 robots easier to integrate within machines like the GENiSYS® R. They can work nimbly in tight workspaces, and their small footprint allows optimisation of the surrounding workspace.

Speed and repeatability are also important considerations. Stäubli robots are known for their ability to maintain high speeds without sacrificing performance: The GENiSYS® R can process up to 20 units per minute, depending on container, product, and IPC rate. Several unique attributes make this possible, even when using NSF H1 food-grade oil. Chief among them is Stäubli’s own patented





gearbox, which the company manufactures in-house. This ensures minimum backlash and

unmatched arm rigidity, allowing for extreme repeatability – translating to higher speed,

shorter cycle time, and greater productivity.

Flexibility from Opening to Closing

Depending on the level of automation desired within the GENiSYS® R system, the TX2-40 and TX2-60 Stericlean robots can handle or assist with critical steps in each stage of the aseptic process: bag and tub opening, filling, stoppering, sealing/closing, and reject handling. If some tasks along the production line need to be manual, the GENiSYS® R can easily accommodate that need while ensuring operator safety and product sterility.

The robots offer reliable repeatability in their motions as they carefully manipulate the nest and vials, which is essential to reducing particle generation, air disturbance, unexpected vial shaking, and other potentially damaging variables. This helps prevent spills and other incidents that would otherwise result in unplanned manual interventions, which risks compromising the aseptic environment.

The use of the Stäubli robots engineered for use in aseptic environments and endowed with exceptional dexterity play a significant role in the GENiSYS® R's high flexibility, enabling the precise filling and closing of ready-to-use nested, pre-sterilised vials, syringes and cartridges. Without these advanced robotic capabilities, the changes between recipes and formats demanded in small batch processing would be impossible or prohibitively complex.

Stäubli Robotics

Stäubli Robotics is a leading global player in robotics, consistently delivering engineering as effective and reliable as our service and support. A complete solutions provider for digitally networked production, Stäubli offers a broad range of 4- and 6-axis robots including robotic arms designed specifically for sensitive environments, autonomous mobile robots, driverless transport systems (AGVs) and cobots for human-robot collaboration.

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