Speed and Precision in Vial Handling

HOF Sonderanlagenbau GmbH took the opportunity of the Achema 2022 trade show to unveil a new loading and unloading system for freeze drying vials in pharmaceutical production – an innovation that epitomizes the finest in conveying and handling technology. The combination of magnetically propelled "movers" and two high-precision, ultra-fast Stäubli Stericlean robots is truly impressive.

Freeze drying is the preservation method of choice for many pharmaceuticals that are supplied in vials for transfer to syringes in hospitals and doctors' offices. This requires that the small vials are filled with the active ingredient and dried partially sealed in a freeze dryer.

Core Competence: Freeze Drying of Pharmaceutical Products

For the past 30 years, freeze dryers for pharmaceutical production have been the core competence of HOF Sonderanlagenbau GmbH, a company based in the small town of Lohra, southwest of Marburg in Hessen, Germany. HOF freeze dryers have been installed by many prominent pharmaceutical and biotechnology companies around the world, and the scope of supply often includes peripheral loading and unloading systems developed in-house.

As a technology leader in the highly specialised and sophisticated field of custom-engineered pharmaceutical production systems, HOF continues to set the benchmark for performance and degree of automation in freeze drying as well as associated loading and unloading systems. A recent example of this is the SIRIUS robot-assisted loading and unloading system which HOF unveiled for the first time at Achema 2022.

Fast, Flexible and Gentle on the Product

Just one look at a SIRIUS system in operation reveals that the HOF design team has developed something fundamentally new. The vials arrive from the bottling line in large numbers, with their caps only loosely attached. Magnetic movers then gently yet rapidly funnel them in nests of five into an oval circuit positioned in front of the freeze dryer, where two compact Stäubli TX2-60 Stericlean six-axis robots with special grippers developed by HOF wait to pick up 50 vials at a time.

When 10 movers, each with five vials, have parked themselves at the loading station, the robots take turns lifting the 50 vials from the movers and placing them on the shelf of the freeze dryer. It's a breathtaking spectacle: If just one of the approximately 13,000 vials per shelf were to topple over, it would trigger a disastrous domino effect, entailing costly product loss. Fortunately, however, this does not occur; the vials do not even touch each other, thanks to HOF's engineering expertise and Stäubli's high-precision robots.

From Magnetic Mover to Robot Gripper and Back Again

This reliability applies both to loading the freeze dryer and to the unloading stage, which is assisted by a pusher mechanism. Here, the TX2-60 Stericlean also unerringly picks up 50 closely packed vials and places them quickly and precisely onto the movers, which then transport them to the crimping machine for sealing.

The manufacturer specified that the vials should not touch each other at any point in the transport stage, and not just for fear of them knocking against each other and spilling their high-value contents. As Peter Schneider, Sales Management Loading and Unloading Systems points out, "Unsealed vials with sensitive active pharmaceutical ingredients are being handled here. That's why we work in an aseptic area – in an isolator or a RABS (Restricted Access Barrier System) – and why we have to avoid any particle generation. This includes glass contact."

Up to 400 Vials Per Minute Under Aseptic Conditions

For this very reason, the robots must also meet all aseptic requirements for working in a Class A cleanroom environment. They do indeed comply, and because HOF chose the Stericlean model, they achieve a long service life despite the intensive cleaning processes prevalent in pharmaceutical production.

The performance of the SIRIUS system, particularly the magnetic movers and the two robots, is truly remarkable. "The target set for the design team was a loading and unloading capacity of up to 400 two-millimeter (2R) vials per minute," says Schneider. "Consequently, one loading/unloading cycle had to take no longer than 14 seconds. We met our target."

Exacting Demands in Safety and Flexibility

One prerequisite for achieving this target is the precision with which the robots place the vials on the shelf of the freeze dryer and subsequently retrieve them. The TX2-60 Stericlean has a repeatability rate of ± 0.02 mm, so everything is within the green zone here.

But the paramount factors are safety and reliability. "A safe and reliable process, both for the product and the operator, is the most important requirement," says Schneider. "In addition to machine and workplace safety, this includes reproducibility and, of course, pharmaceutical cleanroom compatibility." The senior management at HOF also appreciated the support Stäubli provided during the development phase in the form of advice and suggestions for optimisation based on simulations and feasibility studies.

Readily Adaptable to Different Types of Vials

Another primary consideration in the design of the system was flexibility. As Schneider explains, "There are many different formats and standards for vials, ranging from 2R to 100H. SIRIUS is able to handle all of them."

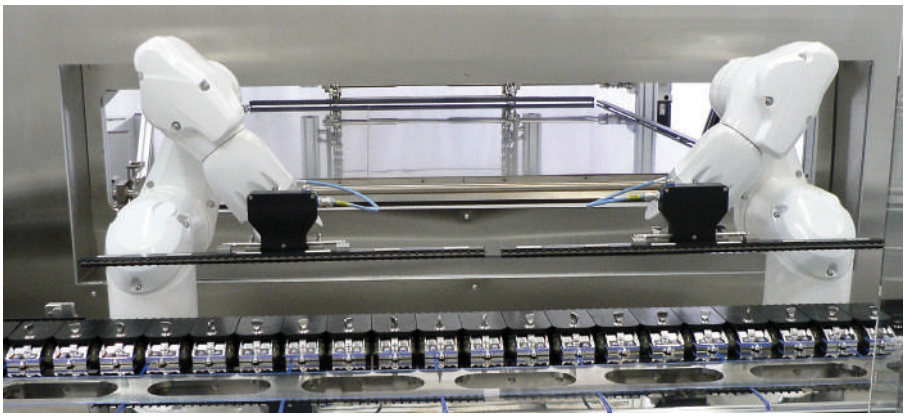
This is facilitated in part by the Stäubli robots' CS9 controller, which stores the format-specific movement paths and points. In the case of SIRIUS, the CS9 is connected to a Siemens PLC over a PROFINET (Process Field Network). The direct programming of the robot's movements is carried out using VAL3 software; the robot control system receives current product-specific data from the PLC. The operating status is displayed clearly for the operator.

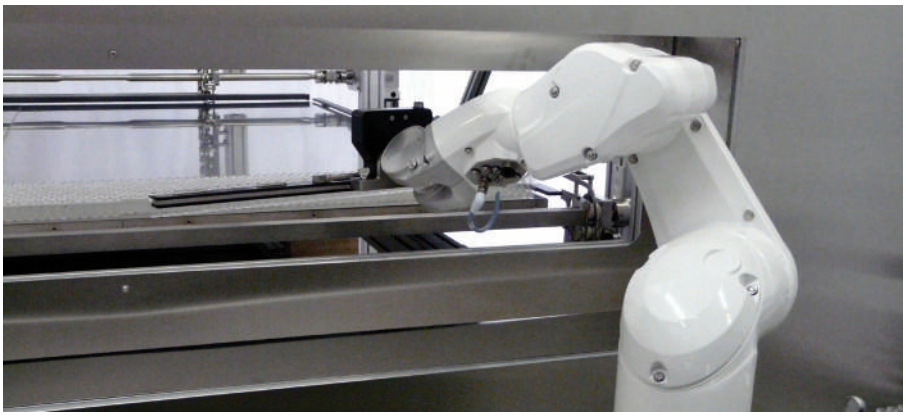
Company Standards for Robotics

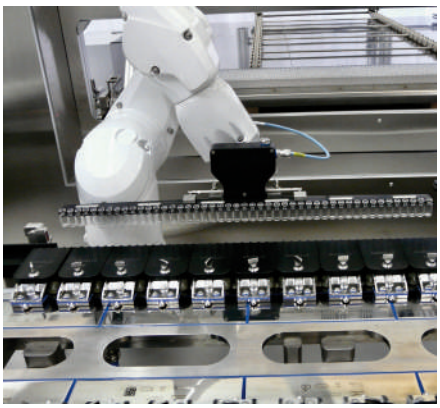
The choice of robot was easy for the HOF designers here, and indeed in all of their other projects. Because robots are integrated

into many of the systems they supply, the company has defined standards for robotic applications and, with a view to the requirements of the pharmaceutical industry, has opted for the Stericlean models from Stäubli.

HOF can use these robots in any pharmaceutical application, no matter how challenging, because they have been specially developed to operate in GMP (Good Manufacturing Practices) Class A aseptic environments, where they have proven their worth time and time again. All the designers have to do is specify the appropriate model plus any optional features.







With its clear advantages, ultra-compact form and modular configuration, the SIRIUS system sets a new standard in fast and reliable loading and unloading of freeze dryers with vials under cleanroom conditions. Even before making its debut at Achema 2022, the prototype had completed extensive tests under practical conditions. The feedback from potential customers was excellent. SIRIUS surely has a great future ahead of it.

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Stäubli Robotics

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