Effective Sterile Powder Transfer for Parenteral Drug Products

Introduction

Personalized medicine is an evolving field — offering targeted solutions that benefit patients by minimizing side effects and increasing effectiveness. This introduces a need for specialized fill-finish equipment that can efficiently route product into final packaging in an aseptic manner.

Parenteral medications are often packaged in one of two forms: an aqueous solution or a dry powder that is dissolved in a solvent prior to administration. While both forms present unique challenges, powder products are particularly difficult to fill in an aseptic environment.

One of the key requirements for a Grade A level (ISO 5) environment is low particulates. Handling a powder product, which inherently generates particulates, requires precise control.

This case study examines how Evonik, a leading global contract development and manufacturing organization (CDMO), improved its powder transfer process for parenteral drug products without compromising efficiency or safety.

Filling Powder Products in an Aseptic Environment

Evonik specializes in complex parenteral medications. Its facility in Birmingham, Alabama, manufactures using fill-finish lines designed to handle any number of products, each with its own specific needs.

The most recently qualified line at Evonik's facility is the VarioSys® production system. The VarioSys® fill line offers high output and flexibility, with options to fill both powder and liquid products in an aseptic environment. VarioSys® is optimized for continuous filling and efficiency, allowing the product to move through the fill line in the shortest amount of time.

Maintaining Quality and Safety

Streamlined product filling is ideal for high-output manufacturing and requires a method to continuously add product to the fill machine without disrupting the line operation. When working with a variety of clients, it is difficult to transfer product from a container to the filling equipment without exposing it to a non-aseptic environment.

Eliminating product exposure is not only critical to the sterility of the product and therefore the patient, but also to the operators directly handling the product vessels and making the connections. Powder products form clouds of dust when released and can harm operators, especially when working with products with low occupational exposure limits.

With the flexibility incorporated into the rest of the VarioSys® fill line, Evonik needed an equally flexible solution to continuously supply powder products to the isolator without compromising sterility or operator safety.

The STERIS VHP® 1000ED Biodecontamination Unit Decontaminating the ChargePoint AseptiSafe Bio Valve®

ChargePoint AseptiSafe Bio Valve® Integrated into Evonik's Isolator Process

Selecting a Vendor

After reviewing multiple solutions, Evonik selected the ChargePoint AseptiSafe® Bio Valve due to its STERIS Vaporized Hydrogen Peroxide (VHP®) biodecontamination capability. This provided Evonik with the highest degree of product protection by maintaining a Grade A level (ISO 5) environment within the sterile flow path.

The ChargePoint AseptiSafe® Bio Valve is compatible with STERIS's VHP® 1000ED Biodecontamination Unit, a versatile and portable VHP® machine with the flexibility to decontaminate a variety of enclosure types and adapt to manufacturing process requirements.

Mobile units are ideal in cleanrooms with limited space because they can be completely removed from the room when not in use. This allows for process-specific equipment to occupy the area and free up the VHP® unit to decontaminate other enclosures.

STERIS also offers integrated VHP® products that can be installed outside of the cleanroom space and piped to the target decontamination area, which is ideal for applications needing dedicated VHP® to a biodecontamination process or space.

Process Improvement

During extended filling processes, it is common for product containers to be replaced when one is emptied. The ChargePoint AseptiSafe® Bio Valve and STERIS's VHP® 1000ED Biodecontamination Unit unit allow this to occur aseptically and under one hour, which is critical to sustaining line operation.

The ChargePoint AseptiSafe® Split Butterfly Valve design completely closes off the connection to the product container and the isolator, which maintains sterility throughout the entire process. From there, the new container is connected, and STERIS's VHP® 1000ED Biodecontamination Unit unit performs a decontamination cycle that lasts approximately 45 minutes. Following the cycle, the filling equipment is reloaded with new product and the filling continues without interruption.

For a single client, the ability to aseptically connect and disconnect the product vessel promptly is crucial to the performance of its powder active pharmaceutical ingredient (API). The product vessel has a high tendency to bridge and is prone to clumping when not flowing. This becomes problematic when the ChargePoint AseptiSafe® Bio Valve is closed with the product resting within the vessel. To combat this, the product vessel is disconnected and inverted periodically to provide gentle aeration to the product and improve flowability.

Summary

As a CDMO focused on providing the highest quality solutions, systems such as the powder transfer technology of ChargePoint and STERIS VHP® provide Evonik with high-value, lasting partnerships that lead to effective service.

"The STERIS VHP® 1000ED Biodecontamination Unit has allowed Evonik to dramatically decrease turnaround time when running high-volume powder filling projects that require multiple product containers," said Caroline Hand, Production Engineer at Evonik. "The combination of the ChargePoint AseptiSafe® Bio Valve and VHP® 1000ED Biodecontamination Unit has allowed us to maintain the highest integrity when performing aseptic product transfer in compliance with EU GMP Annex 1."

References

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ChargePoint Technology Ltd., Venture Point Business Park, 58 Evans Rd, Liverpool, L23 9PB, United Kingdom.

STERIS, 5960 Heisley Road, Mentor, OH, 44060, United States.