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ASEPTIC TECHNOLOGIES' VALIDATED CONTAINER CLOSURE SYSTEM OFFERS IMPORTANT SOLUTION FOR FILL AND FINISH IN CELL AND GENE THERAPY PRODUCT MANUFACTURING

The company's vial closure system provides a sterile barrier against contaminants and maintains product quality even with freezing and cryopreservation.

LES ISNES BELGIUM, NOVEMBER 12, 2020 – Aseptic Technologies today published a white paper, Container Closure Integrity at Cryogenic Temperatures: How the AT-Closed Vial® ensures safe cryopreservation of novel therapies, validating that the company's AT-Closed Vial is the first closed ready-to-fill container that provides a sterile barrier against contaminants and maintaining the quality of cell and gene therapy products throughout their shelf life. The AT-Closed Vial provides absolute resistance to cryopreservation and low temperature storage techniques commonly used throughout the manufacturing process for novel biological products. Aseptic Technologies focuses on state-of-the-art filling technologies, equipment, and devices for the pharmaceutical industry.

"A growing number of cell and gene therapies hold the promise of life-changing treatments for millions of patients. But the manufacturing process for these advanced therapies also creates challenges. Cryopreservation, for example, can impact the quality of the drug product from development and manufacturing through its infusion to the patient," said Jean-Sebastien Parisse, commercial director, Aseptic Technologies. "Our Closed-Vial Technology delivers a comprehensive solution for the fill and finish step of cell and gene therapy product manufacturing, including absolute resistance to cryopreservation."

The container closure integrity (CCI) of the AT-Closed Vial system at cryogenic temperatures and at storage at -80°C has been validated and demonstrated using various testing methods. CCI is defined as the ability of the container system to provide a sterile barrier against contamination and to maintain the product quality throughout the shelf life.

About the AT-Closed Vial Technology

The AT-Closed Vial consists of two core elements: 1) the specially designed ready-to-fill polymer vial, molded and closed in ISO 5 conditions, and 2) the validated filling process, minimizing contamination risks. AT-Closed Vials are delivered sterilized and ready-to-use at the end-user site.

The aseptic filling process using AT-Closed Vials is performed in grade A environment in three steps: first, the stopper is pierced by a sterile needle to inject the drug product into the vial. Once the needle is withdrawn, the stopper mechanically recloses due to of the elasticity of the stopper material. Subsequently, the closure integrity of the vial is restored by applying a one second laser shot on the top surface of the stopper, re-sealing the needle trace. Finally, a sterile cap is snapped-on to protect the septum of the vial until its use at the clinical site. This technology allows:

- a functionally closed filling process, avoiding the risks of airborne contamination from the environment which can occur with a traditional open process (e.g., open glass/plastic vials)

natural scalability from manual to fully automated processes

- fast filling, minimizing product exposure to the cryoprotectant (protecting biological tissue from freezing damage)
- robust Container Closure Integrity (CCI) during cryogenic storage

"Thanks to proven process scalability, reduction of contamination, and insurance of CCI at cryogenic temperatures, our AT-Closed Vial is an effective and widely used solution for cell and gene therapy product manufacturing," added Parisse.

According to the Alliance for Regenerative Medicine, there are nearly 1,100 ongoing clinical trials in the field of cell and gene therapy globally. By 2025, the U.S. Food and Drug Administration (FDA) anticipates that there will be 10 to 20 cell and gene therapy products approved annually, allowing larger patient populations to access these transformative treatments.

For a copy of the White Paper, please click here.

About Aseptic Technologies S.A.

Aseptic Technologies, part of SKAN Group, is a globally acting developer and manufacturer of fill and finish solutions for novel biotechnology products. Within last 10 years, AT has accompanied over three hundred sponsors in the cell and gene therapy field, contributing to their scaling-out or scaling-up manufacturing strategy either in-house or transferred to a third party, gaining a tremendous experience in de-risking of the process and providing absolute resistance of the filled vials during cryopreservation.
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