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AST's GENiSYSÃ?Â® C Fill-Finish System Installed at Ascend's Alachua Facility to Boost Gene Therapy Production

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Next-generation, fully automated fill-finish system enhances Ascend's GMP manufacturing capabilities, supporting high-yield, high-quality gene therapy production in Florida's growing biotech hub.



AST, a leading provider of flexible aseptic filling systems, has announced the placement of a next-generation **GENiSYS® C fill-finish system** at the **Ascend Advanced Therapies (Ascend)** Alachua, FL facility. Ascend is a global gene to GMP gene therapy development partner with **58,500 square feet of recently acquired GMP manufacturing space in Alachua**, a rapidly growing biotech hub and birthplace of AAV gene therapy. The new fully automated and isolated filling and closing line will be installed as part of the commercial infrastructure expansion of the Ascend Alachua facility.

The GENiSYS C is a fourth-generation fill-finish system designed to meet and exceed regulations, including the latest EU Annex 1 Manufacture of Sterile Products, and can be configured to customer needs. The automated, multi-format filling and closing system can process commercial and custom nested vials, syringes, and cartridges on a compact, no-touch production line. Fully automatic bag and tub opening, filling/closing, and vial sealing with pharmaceutical-grade aluminum capping minimize operator interaction. The fully integrated system is American-built and serviced, featuring isolator barrier technology designed in collaboration with **Germfree**, and groundbreaking bio-decontamination technology from **CURIS System** to enhance process safety and product quality.

“One of our core differentiators at Ascend is the level of investment in people and enabling technologies that we continue to make,” said Mike Stella, CEO at Ascend. “After extensive evaluation, we chose the GENiSYS C fill-finish system due to the ability to configure it to our needs and the support offered from the AST project management and aftermarket teams. In addition to being able to customize our machine, the new integrated GENiSYS C offers benefits like 60-minute cycle times (including aeration), which will have a deep impact on quality and timelines.”

The GENiSYS C placed in Alachua will utilize pre-sterilized, ready-to-use containers and features robotic tub handling and a fully automated filling and closing process to minimize human intervention. Zero-waste processing includes one hundred percent in-process weight checks with no impact to the machine throughput, and end-of-batch filling to avoid product loss. A comprehensive suite of visual and sensor-based quality checks has been customized for Ascend to maximize yield and quality.

“Both AST and Ascend have a clear commitment to flexible, innovative solutions, and that’s what makes this partnership a natural fit,” commented AST President and CEO Joe Hoff. “Ascend has a record of delivering high-yield, high-quality products and AST’s isolated GENiSYS C is a proven system designed to meet the most rigorous standards of product integrity that will aid this work well into the future. We’re thrilled to support Ascend’s crucial mission of bringing more groundbreaking gene therapies into production.”