



ATMP Manufacturing: The AST Way

Background

Ascend Advanced Therapies (Ascend) is a specialist adeno-associated virus (AAV) development partner working to bring next-generation gene therapy products to market. Ascend leverages a flexible platform that supports all AAV serotypes across scales with proprietary and partnered technologies and a world-class analytical toolkit enabling the team to Aim Higher in balancing yield and quality of commercially accessible life-saving therapies.

Ascend's Objective

Ascend sought a flexible, fully-automatic solution configurable to the specific product demands of AAV production to be placed in their new 58,500 square-foot manufacturing space. Identified differentiators included systems with a cGMP design for regulatory compliance (including alignment with Annex 1), advanced technologies prioritizing product quality, time to patient, and project ramp-up and aftermarket support for equipment lifecycle management.

Partnership in Motion

In response to Ascend's request, AST designed a unique, isolated solution that minimizes human intervention and prioritizes product recoverability and maximum yield, designed for seamless integration into Ascend's facility. The AST and Ascend teams are prioritizing clear and responsive teamwork over the course of the project to ensure successful installation and qualification of the equipment.



Approach

- Transparent communication
- Bi-weekly meeting cadence
- Site visits for high-leverage objectives
- Cross-department coordination
- Multi-stakeholder project management
- Milestone prioritization

AST's Solution

To meet Ascend's manufacturing needs, AST is providing a unique isolated **GENiSYS® C** configuration with robotic nest transfer. The 100-percent automated, multi-format filling and closing system can process commercial and custom nested vials, syringes, and cartridges on a compact, no-touch production line. The isolated line feature's AST's **Atmos™** isolator and groundbreaking decontamination technology for 60-minute cycle times, including aeration.

This fully integrated system is American-built and serviced, and will be placed in the Ascend Alachua facility.

Ready to get started? Visit us at ast-inc.com.