



# Providing Flexible Aseptic Solutions: The AST Way

## Background

Catalent is a global leader in providing integrated services, superior delivery technologies, and manufacturing solutions to help life science innovators develop and launch successful pharmaceuticals, biologics, and consumer health products.

## Objective

Catalent Cell and Gene Therapy searched for a cGMP aseptic filling and closing machine that can reliably process a wide range of both trayed and nested vials for their current client product needs. Catalent decided on AST as a trusted partner to provide two GENiSYS® R systems to install in one of their U.S. commercial-scale facilities. One of the machines required expedited delivery to support their growing cell and gene therapy customer demands.

## AST's Solution

AST swiftly assessed their capacity to meet Catalent's needs and provided them with a design that met the specifications for their new expansion. This project's success requires open communication and transparency.

To achieve this, all responsible departments from both parties participate in weekly meetings to proactively progress the project according to the agreed upon schedule. As the project progresses, AST collaborates with Catalent to ensure successful installation and qualification.

## Catalent®

## Approach

- Responsive communication
- Weekly meetings
- Multi-department effort
- Transparency
- Prioritizing critical tasks

## AST's Machines

To fulfill Catalent Cell and Gene Therapy's aseptic manufacturing needs, AST is delivering two GENiSYS® R systems that will be configured with semi-automatic bag opening, tub and trayed vial handling, robotic filling/closing, and vial sealing. The system configurations will include aseptic isolator barriers, innovative 100% IPC weigh check, and EBR systems offering robust and reliable data to meet Catalent's customer needs for both cGMP and data integrity compliance.

Not only does this meet all of Catalent's needs, but this will also give Catalent the flexibility to fulfill a wide range of projects and provide the sterility assurance their customers' products require.