



Your world leading CDMO.

## Robotic Sterile Fill-Finish Services

**As a world class CDMO, we relentlessly strive to deliver better health outcomes for the patients we serve by combining our experience and expertise in science, manufacturing, and technology with our pristine customer service.**

To complement our existing sterile fill-finish capabilities, we have further invested in state-of-the-art robotic technology. This investment comprises two Cytiva Microcell Vial Filler units for earlier clinical scale manufacture and a larger scale Cytiva SA25 Aseptic Filling Workstation for later stage clinical through to commercial launch scale manufacture. The scalability of our robotic service offering from the Microcell Vial Filler through to the larger SA25 Filling Workstation allows us to plan for delivery of larger clinical and commercial scale production as a product moves through its lifecycle. In addition, as the SA25 technology is able to fill multiple delivery device formats including vials, syringes, and cartridges, we will work with you throughout the early clinical development program to offer a seamless later stage clinical and commercial scale production plan in the most patient-centric delivery format.

### Microcell Filling

This filling technology provides both small batch flexibility and standardized manufacturing with vial filling performed through closed robotic isolator technology. The fast changeover and agility of the technology makes this suitable for both personalized medicine batch production as well as clinical trial supplies.

The agility of this technology means reduced fill and changeover times, delivering true speed to patients. Superior drug product quality is assured through advanced automation, removing the need for operator intervention during the filling process and limiting product contact through single-use flow parts.



### Key Features of the Microcell Filling Technology

- Fully automated, gloveless GMP filling process
- HMI touchscreen for intuitive access to input and initiate recipe sequences
- Single-use flow paths
- 15 minute VPHP decontamination
- Throughput of up to 1,200 units per 8-hour shift
- Fill volume range 1.0-50mL
- Interior classification Grade A

Together, delivering life changing therapies.

# Overview

## SA25 Aseptic Filling Workstation

This larger scale filling technology offers both small and large scale batch production, with flexible and standardized manufacturing and the ability to fill multiple delivery device formats including vials, syringes, and cartridges through an aseptic process.

As with our Microcell technology, the SA25 delivers superior drug product quality through advanced automation of the filling process, removing the need for operator intervention through single-use flow paths.



## Key Features of the SA25 Aseptic Filling Technology

- No glove ports, minimizing human intervention in the aseptic process
- HMI touchscreen for intuitive access to all process controls, recipes, and batch data
- Complete batch reports and integrated data historian
- Single-use flow paths
- Commercial scale production for multiple dosage forms
- Throughput of up to 20,000 units per batch
- Fill volume range 0.2-50mL
- Interior classification Grade A
- Vial, syringe, and cartridge filling capabilities

## The Benefits of PCI's State-of-the-Art Robotic Sterile Fill-Finish Technologies Versus More Traditional Solutions

- The fastest and safest path to flexible sterile filling for your high value therapies
- The gloveless isolator removes human intervention from the process, achieving the highest standards of sterility
- Robotic accuracy avoids the electro-mechanical filling and closure activity failures typically experienced with more traditional filling technologies
- Sterility assurance and drug product quality is significantly improved as multiple sources of risk are eliminated through single use parts, a pre-sterilized flow path and ready to use containers
- Particle risk is reduced through the use of press-fit vial closures with integrated stoppers – no crimp capping or stopper bowl
- The high precision Dynamic Peristaltic Pump ensures accurate fill volumes with minimal product losses – our equipment is designed to reduce shear stress and prevent aggregation that is often seen when processing biologics
- The agile technology delivers reduced fill and changeover times

