cytiva

Aseptic filling with Cytiva: Just the facts

Solving aseptic filling challenges for your advanced therapeutics

Fact:
Today's multi-modality, small-batch ecosystem poses new challenges for aseptic filling. Technology for large-batch blockbusters is too complex. And manual filling doesn't offer the needed speed, consistency, and sterility – nor the peace of mind that you will continue to meet ever-evolving regulatory guidelines.

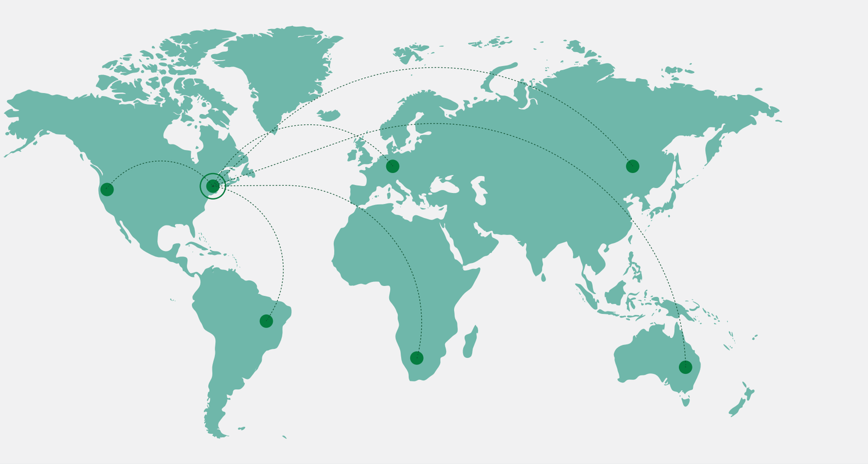
Many therapeutic modalities

Oncolytic viruses, DNA & RNA therapies, Microbiomes, Proteins & peptides, RNAi, PROTAC, mAbs, BsAb, Gene therapies, mRNA

Multiple formats

Speed to market

Global production



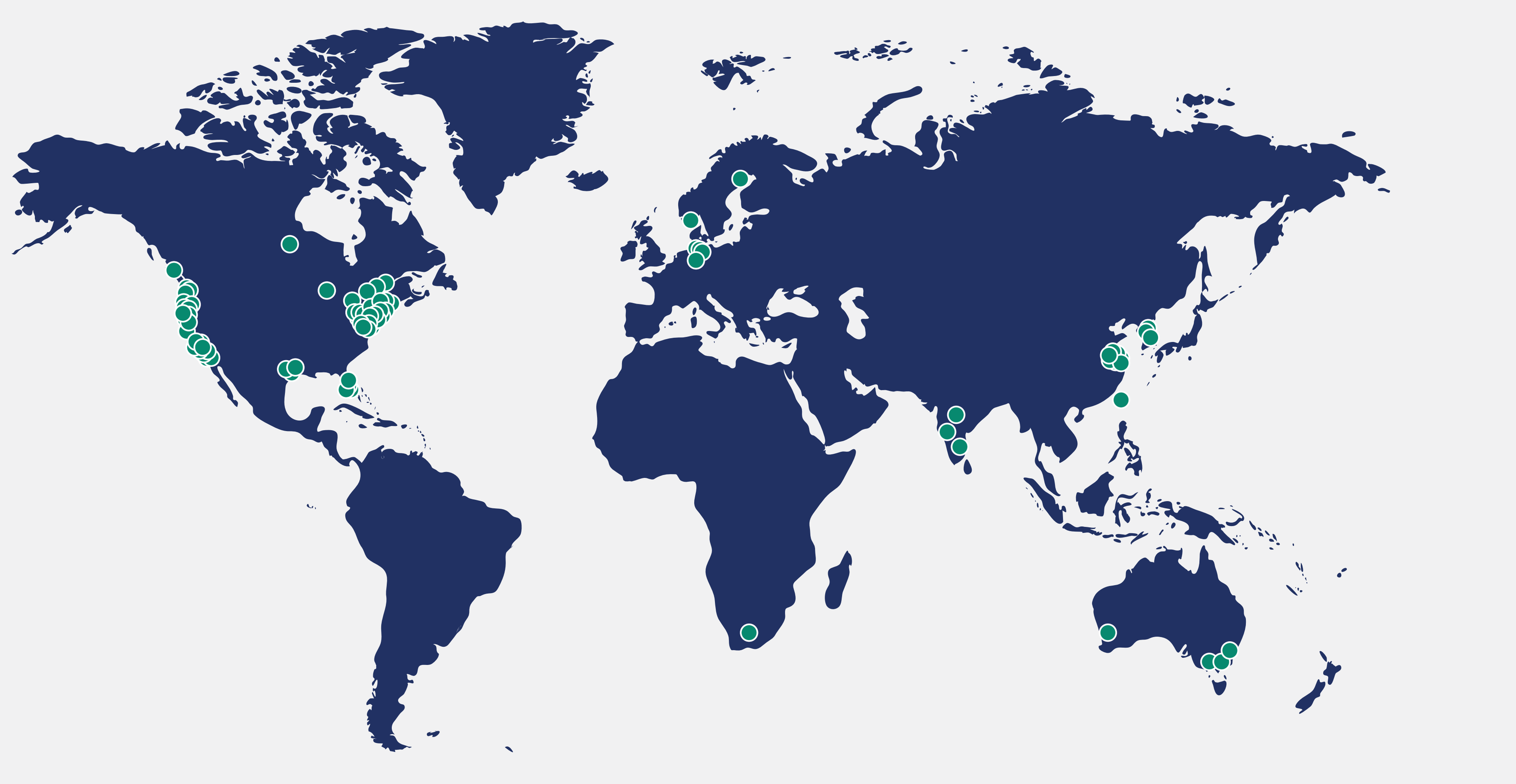
Breaking with tradition to rethink aseptic filling

Fact:
Manual processes involved in traditional aseptic filling come with risk—operator contamination, poor airflow, open environments—making true product isolation impossible. In 2007, our founders, a microbiologist and an engineer, envisioned a gloveless, robotic isolator that would solve these challenges and greatly improve on traditional aseptic filling techniques. As a result, the SA25 aseptic filling workcell and its companion Microcell™ vial filler were born and have been adopted widely for clinical and commercial drug product filling.

65+ robotic workcells sold globally

4+ Agencies approved commerical drug products filled on Cytiva workcells

65+ aseptic filling workcells sold across five continents



Used to fill commercial products approved by the US Food and Drug Administration (FDA), Health Canada, PIC/S and NMPA (China)*

*PCI/S: Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme. NMPA: National Medical Products Administration (China).

Exceeding conventional standards to give you confidence in your fill

Fact:
Complying with regulatory guidelines for aseptic filling has become more complicated everywhere. Our standardized, gloveless isolator filling systems support your workflow by meeting the strictest guidelines for the manufacture of sterile injectable drug products in accordance with both the US Food and Drug Administration and European Union's Annex 1 good manufacturing practice (GMP) guidelines.

Facilities flexibility
Small footprint requires less cleanroom space than manual isolator configurations

Container flexibility
One system for vials, syringes, cartridges, no separate modules

Speed to the market
PO → 6 months → FAT → 6 months → Installed and qualified

Aseptic assurance
- **Gloveless isolator** with very low particle levels
- **Repeatable** robotic production
- **Continuous** positive pressure airflow
- **Continuous** environmental monitoring with biofluorescent particle counting
- **Grade A** conditions with continuous, positive pressure, unidirectional airflow

Designed to eliminate 95% of causes for interventions

Process flexibility
1 hour → Start-up including decontamination
→ Changeover between formats

Comprehensive services
- White-glove qualification
- Regulatory service support
- OptiRun™ service solutions, including service contracts

Strategic flexibility
- **Scalable** from preclinical to commercial
- **Simple** to operate with one operator within small grade C/D space
- **Deploy globally** with standard design

98% of service requests resolved remotely

Creating a community to help you find answers

Fact:
Manufacturing and filling sterile drug products are complicated and challenging endeavors. That's why we created the Cytiva aseptic filling user group, so you can be part of a community succeeding together. What better way to push the envelope than alongside people who've already found solutions to your challenges?

Environmental monitoring study

In 2022, eight of Cytiva's aseptic filling customers co-authored a peer reviewed article[1] concerning environmental monitoring in the SA25 aseptic filling workcell. Here are their findings:

00.0%	failure rate (0 positive units) from 49 media fills, covering more than 175 000 units
>6σ	confidence that non-viable particles fall below the ISO 5 limits
99.3%	dosage unit acceptance rate in more than 1 000 000 units filled across 10 different vial, syringe, and cartridge formats

1. McCall J. Bernard N. Gadient K. Kasireddy C, Kurtz A, Li Y, Page T, Putman T, Brennan, Á, Environmental monitoring for closed robotic workcells used in aseptic processing: Data to support new regulatory approaches. *AAPS A.* 2022.

cytiva.com/aseptic-filling

For local office contact information, visit cytiva.com/contact

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