

Meet the aseptic filling workcell

**Standardized aseptic
filling technologies for
clinical and commercial
drug products**



Advancing drug product manufacturing operations



Robust aseptic process

With aseptic filling workcells, we have designed operator intervention and other risks to drug product quality out of the filling process. The benefits of closed robotic workcells are quantifiable — a study of eight different customer sites found lower risk of contamination and improved dosage yields, compared to conventional aseptic filling systems (1).

Faster to patients

Standardization means aseptic filling workcells can be built and implemented quickly. Average timelines to reach GMP production are between 6-9 months for the Microcell™ vial filler, and 12-15 months for the SA25 aseptic filling workcell. Once in operation, both systems provide a robust aseptic process supported by data to provide sterility assurance. Workcell users also benefit from the shared experience and knowledge of a global user group.

Agile for today's pipelines

Drug products are increasingly targeted at smaller patient populations and are often high value. Aseptic filling workcells provide manufacturers with tools to manage multi-product portfolios and bring new therapies into production with greater ease.

McCall J, Barnard N, Gadiant K et al. Environmental monitoring for closed robotic workcells used in aseptic processing: data to support advanced environmental monitoring strategies. *AAPS PharmSciTech*. 2022 Aug 3;23(6):215. doi: 10.1208/s12249-022-02360-3.

Key features to optimize your aseptic filling operations

No glove ports

We have designed operator intervention out of the system. Robotics perform all material handling, filling, and closing activities inside the isolator.

Fully integrated

Aseptic filling workcells provide a seamless combination of robotics, machine vision, and gloveless isolator technologies. Manage recipes, process parameters, and electronic batch records through a single human-machine interface (HMI).



Improved process capability

Easily modify recipe parameters to suit the needs of different drug products. Recipe-driven automation makes production repeatable across dosage formats. Aseptic filling workcells are also equipped with our dynamic peristaltic pump, which when tested against conventional peristaltic pumps, provided a 10x improvement in precision and accuracy.

65+ aseptic filling workcells
sold across five continents



Aseptic
filling workcells
by the numbers

- Systems installed
- Systems to be installed in 2025



Used to fill commercial products approved by the US Food and Drug Administration (FDA), Health Canada, PIC/S (2), and NMPA China (3)

Multiple customers achieved GMP certification in markets governed by European Medicines Agency (EMA) after August 2023 revision of Annex 1

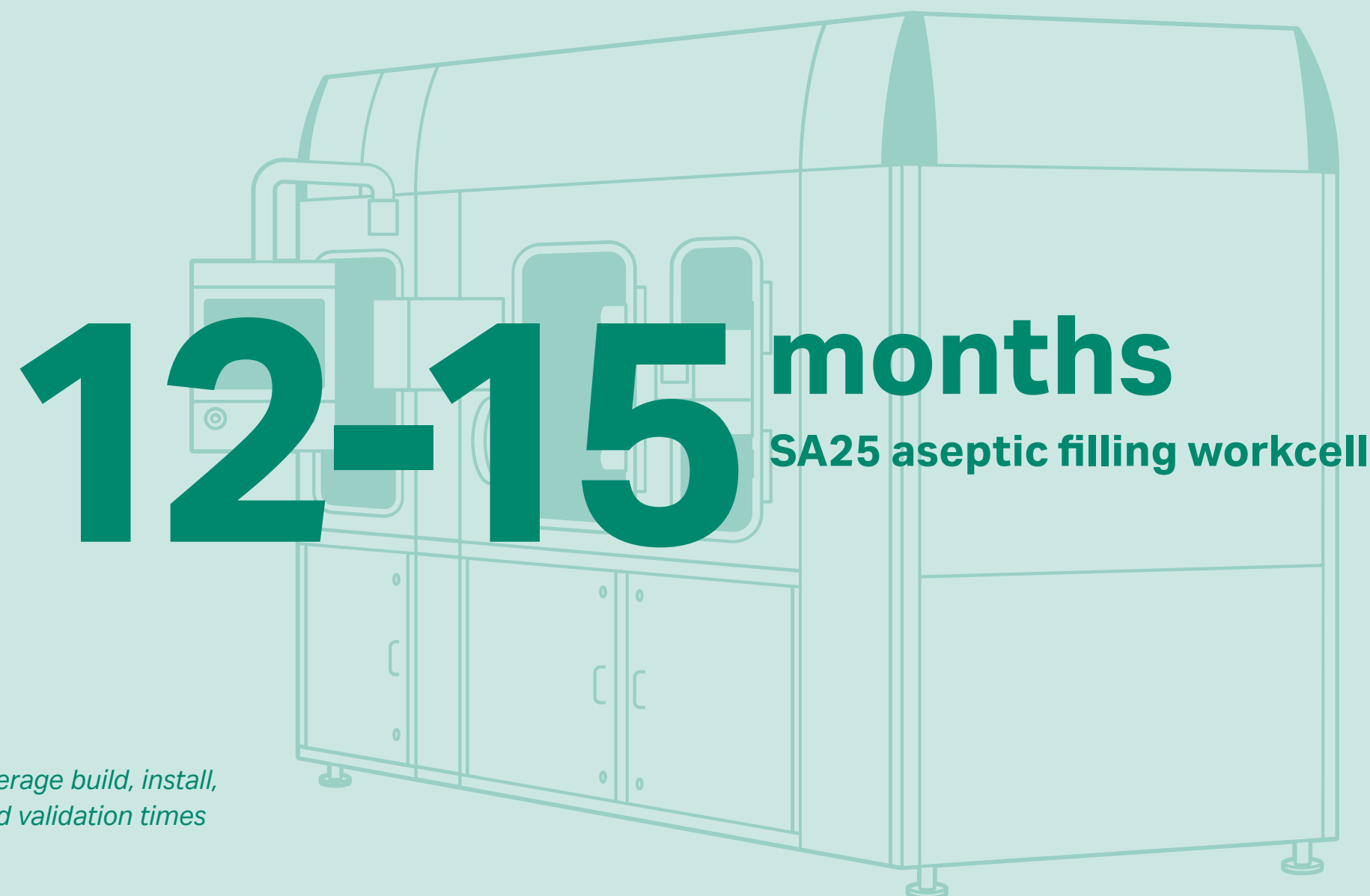
(2) PIC/S, Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme.

(3) NMPA, National Medicinal Products Administration (China).

Speed to patients



9 months
Microcell vial filler



12-15 months
SA25 aseptic filling workcell

*Average build, install,
and validation times*

Aseptic filling workcells by the numbers

Environmental monitoring study

In 2022, 8 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:

0%

failure rate (0 positive units)
from 49 media fills, covering
more than 175 000 units.

>6 σ

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.

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See inside the aseptic process

Limited hazard pathway

Product contact surfaces are limited to the inside of a single-use flow path and the dosage container or closure. This greatly limits the hazard pathway compared to conventional filling systems that use features such as conveyor belts, star wheels, and stopper bowls.

Fully robotic process

Non-particle-creating semiconductor robotics do the material handling, filling, and closing inside the isolator of an aseptic filling workcell. Nested, presterilized components also enable production of multiple vial, syringe, and cartridge formats and sizes.

Contamination control

With no glove ports or human interventions, our contamination control strategy is focused on viable and nonviable particles at key placements in the isolator. A simple interior design supports effective automated vapor-phase hydrogen peroxide and clean-in-place systems.

Aseptic filling systems to meet your needs

Microcell vial filler

For personalized medicines and early-stage clinical trials

Productivity:

Up to 1200 units per 8-h

Formats:

Nested, presterilized 2R-50R (1-50 mL) vials

Who's using it?

- Adaptive Phage Therapeutics and Locus Biosciences use the Microcell vial filler to help deliver personalized bacteriophage drug products to combat antibiotic-resistant bacteria.
- NorthX Biologics uses the Microcell vial filler for clinical trial and commercial manufacturing of advanced therapeutics.
- Eurofins Biopharma Product Testing uses the Microcell vial filler to contract manufacture phase I/II clinical trial materials.



SA25 aseptic filling workcell

Vial, syringe, and cartridge filling for commercial and clinical drug products.

Productivity:

Up to 25 000 units in a 24-h period

Formats:

Nested presterilized vials, syringes and cartridges

Who's using it?

- FUJIFILM Diosynth Biotechnologies uses the SA25 for gene therapy drug products.
- Moderna uses the SA25 for manufacturing clinical trial materials of its mRNA platform technology.
- ADMA Biologics and Emergent BioSolutions use the SA25 for production of US FDA and Health Canada approved sterile injectables.
- Singota Solutions and White Raven use the SA25 to provide CDMO services for vial, syringe, and cartridge filling for clinical trial materials.

A complete ecosystem for customer success



Container and closure collaborations

Since 2016, we have worked with providers of nested vials, syringes, and cartridges, as well as manufacturers of press-fit closures, stoppers and plungers, on combined solutions to ensure final product quality and suitability for our machines.



Single-use consumables

We offer both standardized and customizable single-use options for flow paths, fill needles, filters, and bags.



Your helping hand

We're a global life sciences leader dedicated to helping you advance and accelerate therapeutics. Aseptic filling workcells can be integrated with our FlexFactory™ process train and KUBio™ modular manufacturing solutions.

Want to learn more?

Visit our website to find testimonials, use cases, and product information.

[Learn more](#)

cytiva.com/aseptic-filling

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