Advance pharmaceutical manufacturing

Step into the future of manufacturing technology.

cytiva

Fast. Flexible. Predictable.

Your drug products deserve to succeed. We know how important downstream manufacturing operations are for bringing your products to market quickly and efficiently.

We've worked with experts like you to learn where conventional aseptic filling solutions fall short and how we can improve on them. The result? Aseptic filling technology that's flexible, standardized, and easy to implement. Cytiva Aseptic Filling Workcells are gloveless, robotic isolators that remove operator handling from the filling process — so your products can reach patients faster and with fewer potential risks to product quality.

Top biopharma companies are already using Cytiva's Aseptic Filling Workcells to streamline and future-proof their manufacturing operations. Keep reading to learn how we can help you reduce costs and get your products to patients faster.

What are the challenges of conventional filling technologies?

Unnecessary risk

Conventional aseptic filling technologies require manual intervention through glove ports. We see that as a design flaw that introduces risk to product quality, as it adds a potential source of contamination.

Custom = costly

Custom or modular filling machines can mitigate some flaws of conventional filling technology, but they can also lead to cost overruns, delays, and “do-overs”.

Inflexibility

The biopharmaceutical market is rapidly evolving, but older filling solutions aren’t always designed for agility. This can limit your ability to respond to changes in your pipeline or forecast for different batch sizes or formats.

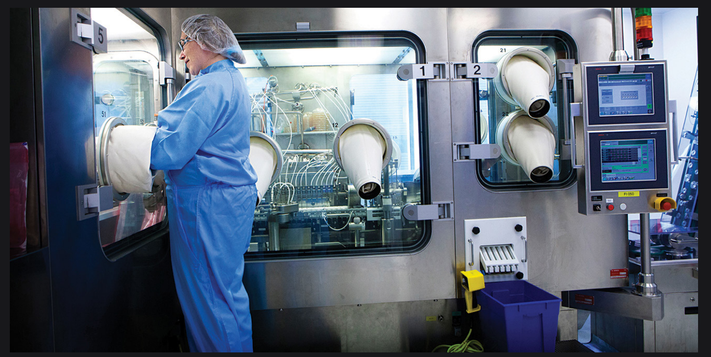
We interviewed leaders like you to understand their pain points. Here’s what they told us:

54% Needed multiple iterations to get it right

46% Dealt with delays

42% Went over budget

From 78 people surveyed by the Linus Group in Q1 2020.



A conventional filling system with glove ports

What's different about Aseptic Filling Workcells?

A closed system for reduced risk

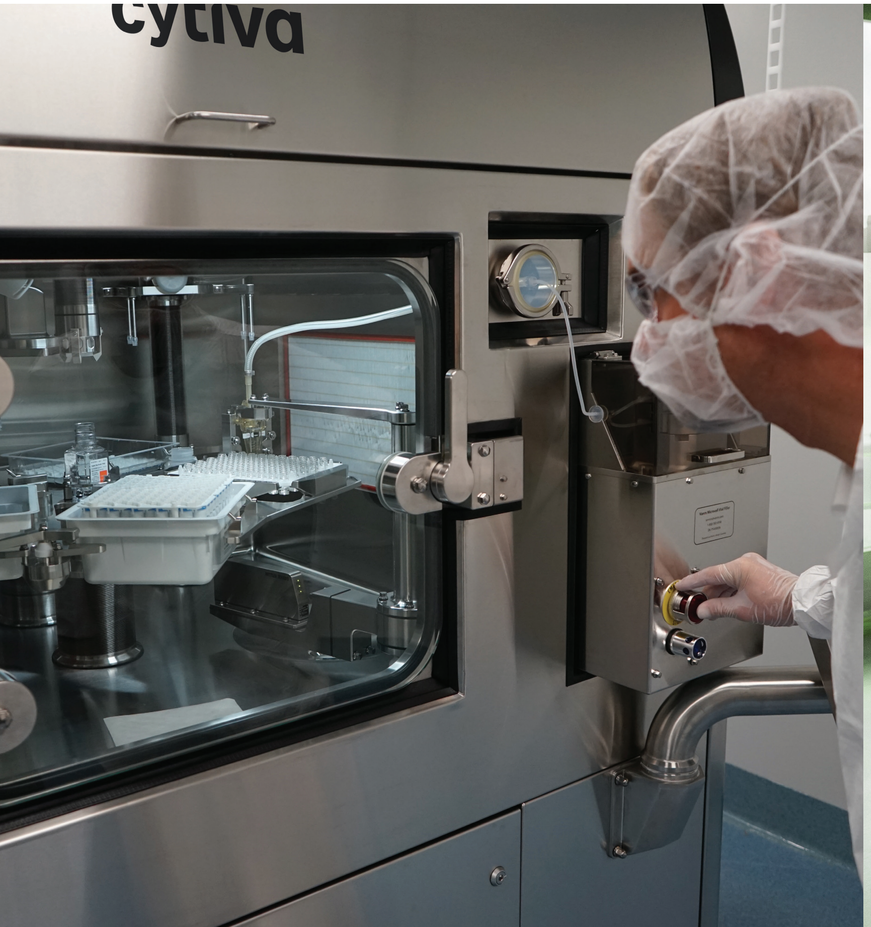
Cytiva Aseptic Filling Workcells are designed to be completely closed. They're built without glove ports, as they don't require operator handling during the filling process. Advanced robotics drive repeatable processes for multiple dosage formats.

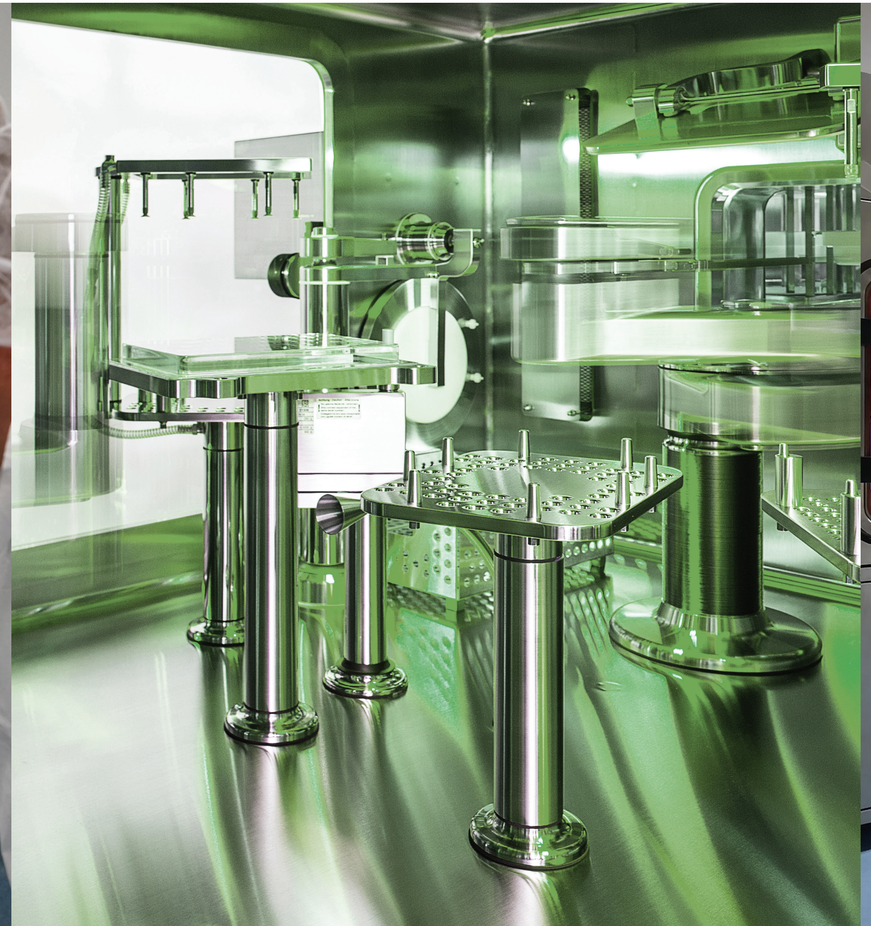
Standardized with built in flexibility

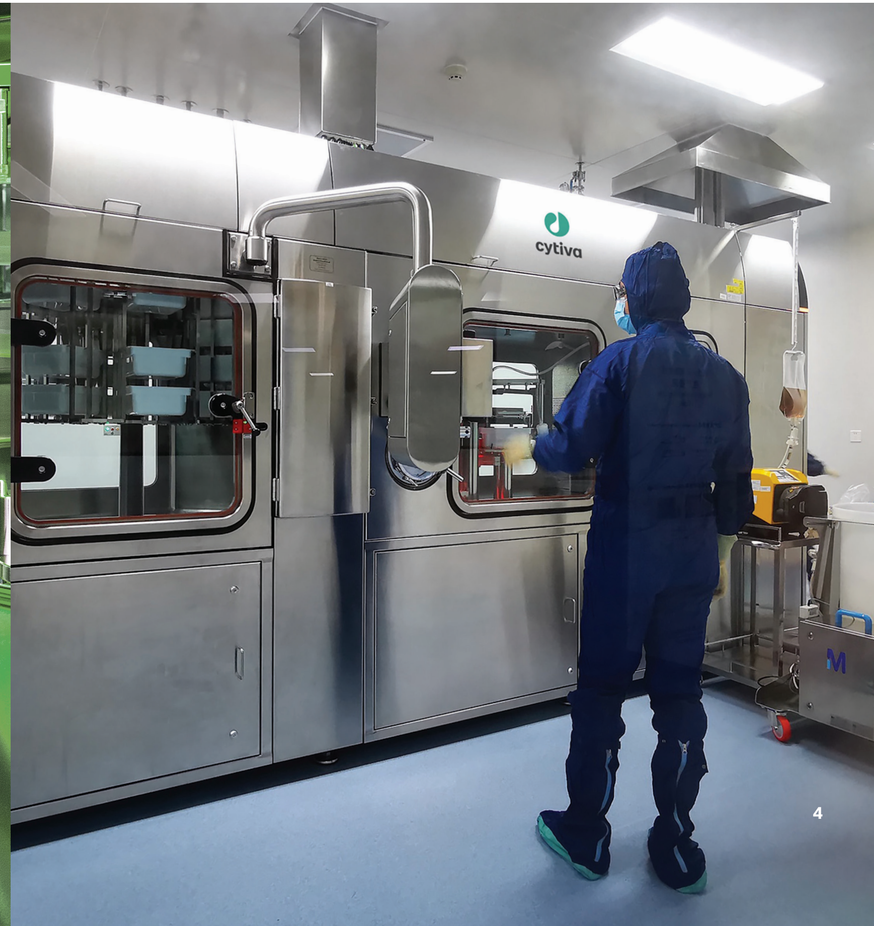
Future-proof your aseptic process with flexibility and multiple dosage formats. Standardization helps reduce unexpected delays and get drug products to patients faster.

Fast lead and implementation times

We build the same standardized machine for every customer, so filling facilities can reach GMP in 6-15 months, depending on the system. This means you can also scale out easily. Capacity can be scaled out with additional machines quickly as candidates succeed in the clinic.







Strategic impact

Flexibility through automation

Aseptic Filling Workcells are adaptable to fill multiple drug types in different dosage formats and sizes. This flexibility is driven by automation and standardized material handling methods.

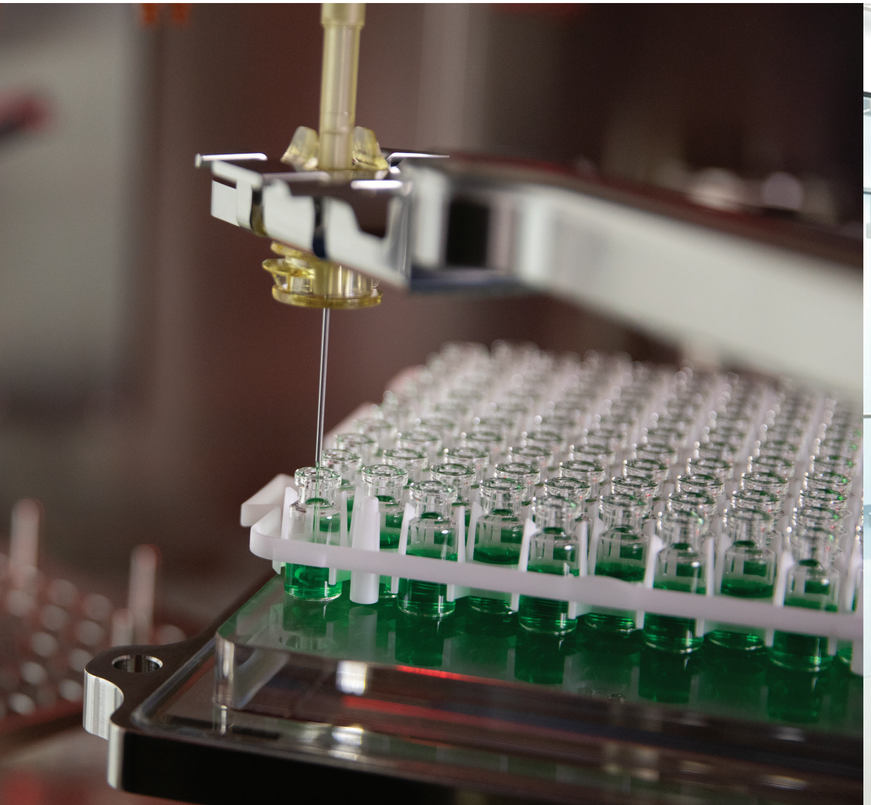
Facility fit

Whether you're filling a single drug product continuously or a different product every day, Aseptic Filling Workcells can support your needs. This is a good fit for CDMOs or when manufacturing diverse pipelines.

Advanced ecosystem

Use Aseptic Filling Workcells to extend the flexibility of your facilities. They're a good fit in supply chains that also include single-use bioprocessing equipment, pre-fabricated modular cleanrooms, or Industry 4.0 systems.

Using nested containers helps keep filling operations flexible, with minimum change parts needed for different formats. They are also crucial to creating completely closed isolators, keeping humans out of the aseptic process.



Operational impact

Closed filling system

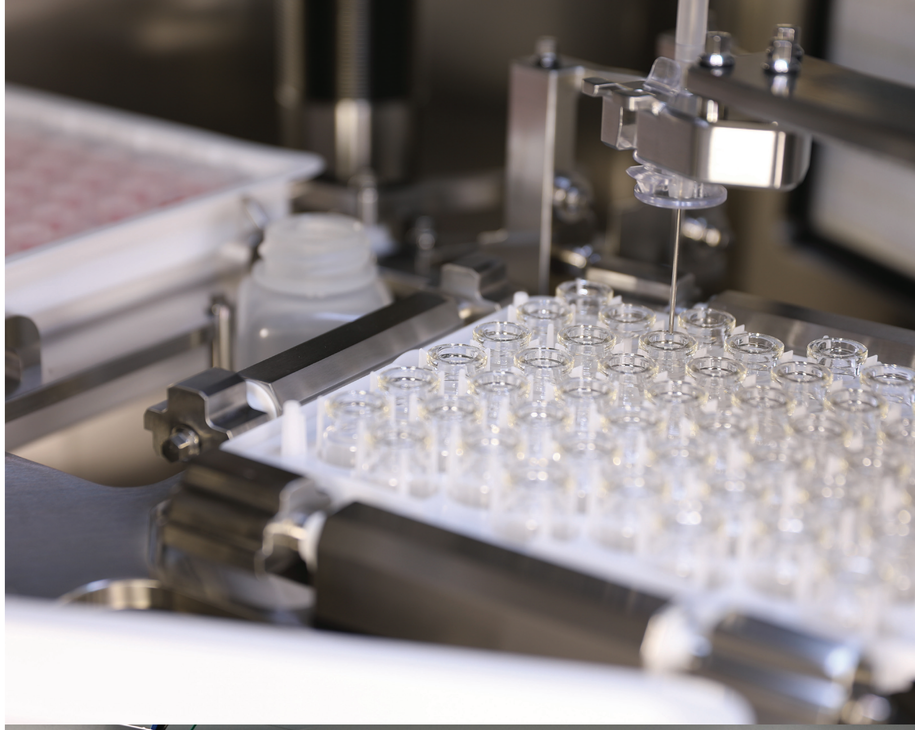
Aseptic Filling Workcells are designed to be fully closed to contain viral vectors or potent compounds. Systems include built-in cleaning systems and decontamination cycles for viral deactivation.

Maximized product yields

Our Aseptic Filling Workcells minimize line loss so you can get more doses from each batch. Customers have reported line losses as low as 12 mL for the Microcell and 25 mL for the larger capacity SA25.

Agility

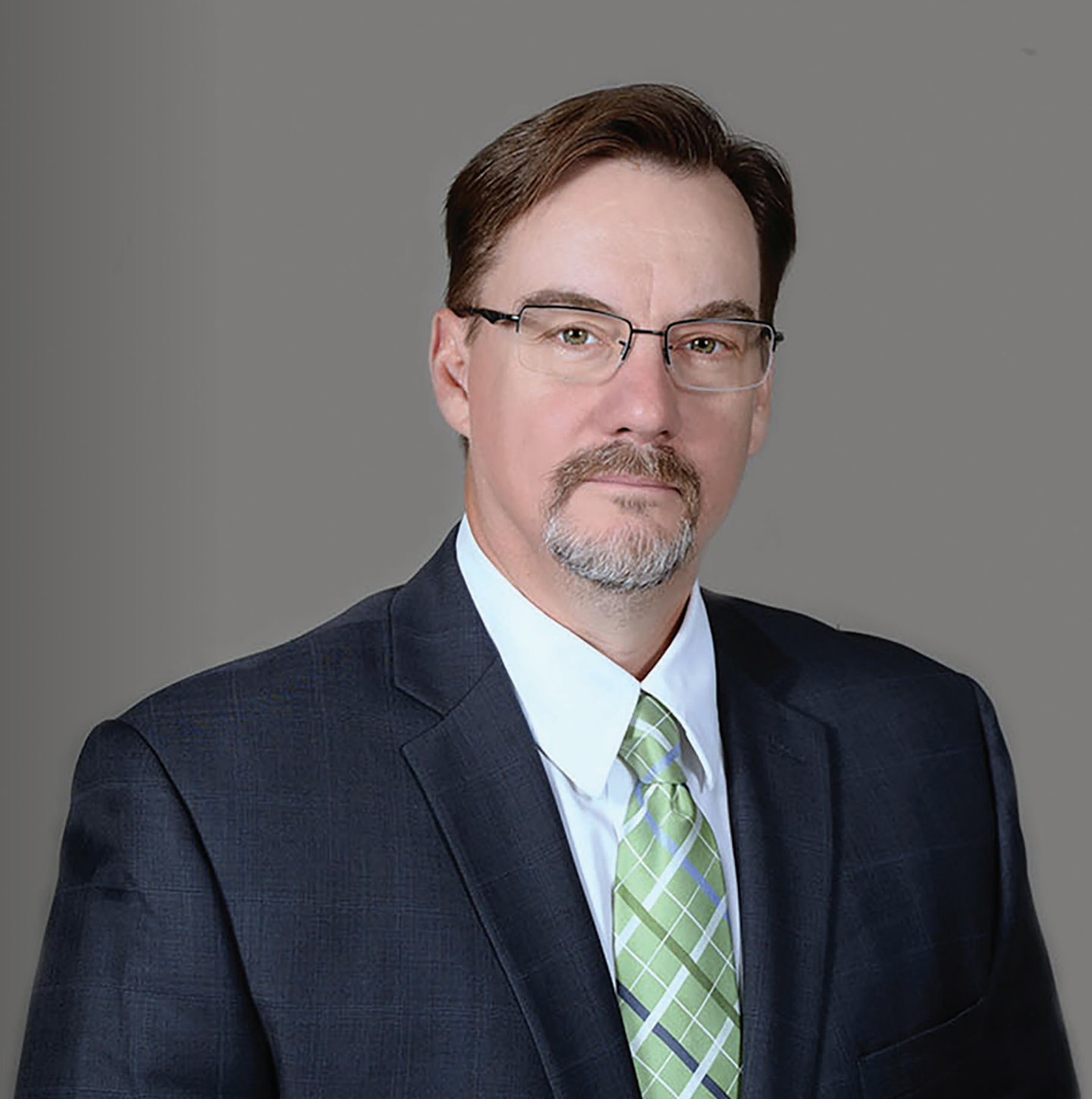
With autologous therapies or those with multiple potential indications, you may switch drug products frequently. Depending on the model, a Cytiva Aseptic Filling Workcell can switch between therapies in as little as 15 to 60 minutes.

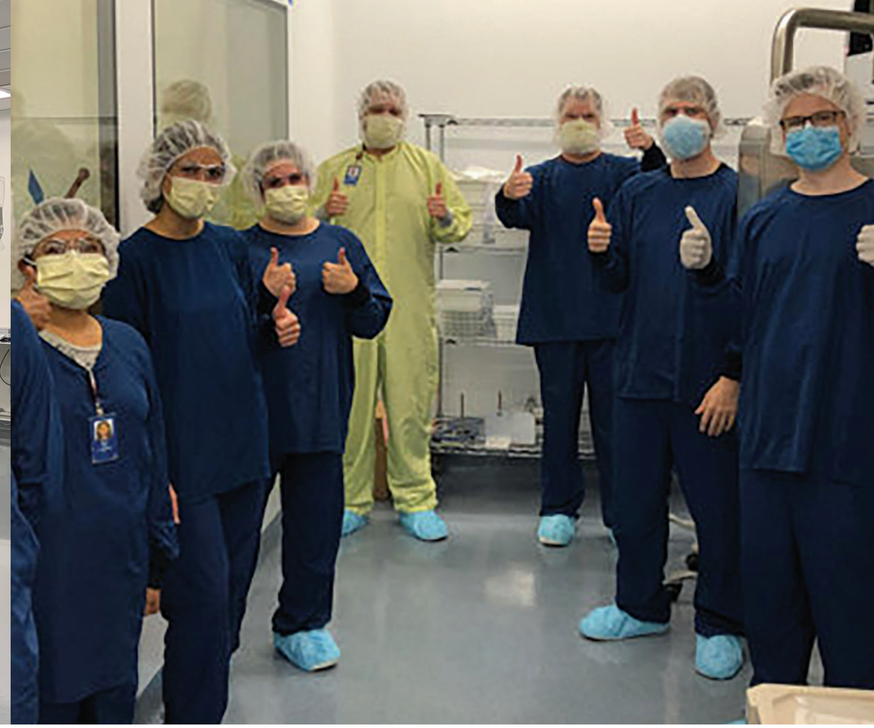


Top: Vial filling within the Microcell, which enables the agile manufacturing of advanced therapies without manual processes.
Bottom: The machine can fill up to four patient specific therapies in a single 8-hour shift.

From the low line loss of our SA25, our customers are getting enough extra vials out of the gene therapy filling process to pay for their entire filling run.

Thomas Page
VP Engineering and Asset Development, FUJIFILM Diosynth Biotechnologies





From left to right: The team at ADMA Biologics, a manufacturer of immune globulin products; the SA25, in use at Moderna for manufacturing clinical trial supplies, including its COVID-19 vaccine; The team at Genentech in Hillsboro, Oregon. Roche and Genentech have installed multiple SA25s and Microcells as they standardize for flexible filling globally.

ADMA Biologics

"The company [Cytiva] has helped us move quickly to receive and install our new filling machine, the SA25 Aseptic Filling Workcell during the COVID-19 crisis. We believe the SA25 is an easy-to-use, all-in-one solution for our in-house aseptic filling requirements and will allow ADMA to bring our products to patients faster, improve our margins, as well as substantially increase our end-to-end control over our manufacturing process." –Adam Grossman, President and CEO, ADMA Biologics.

Moderna

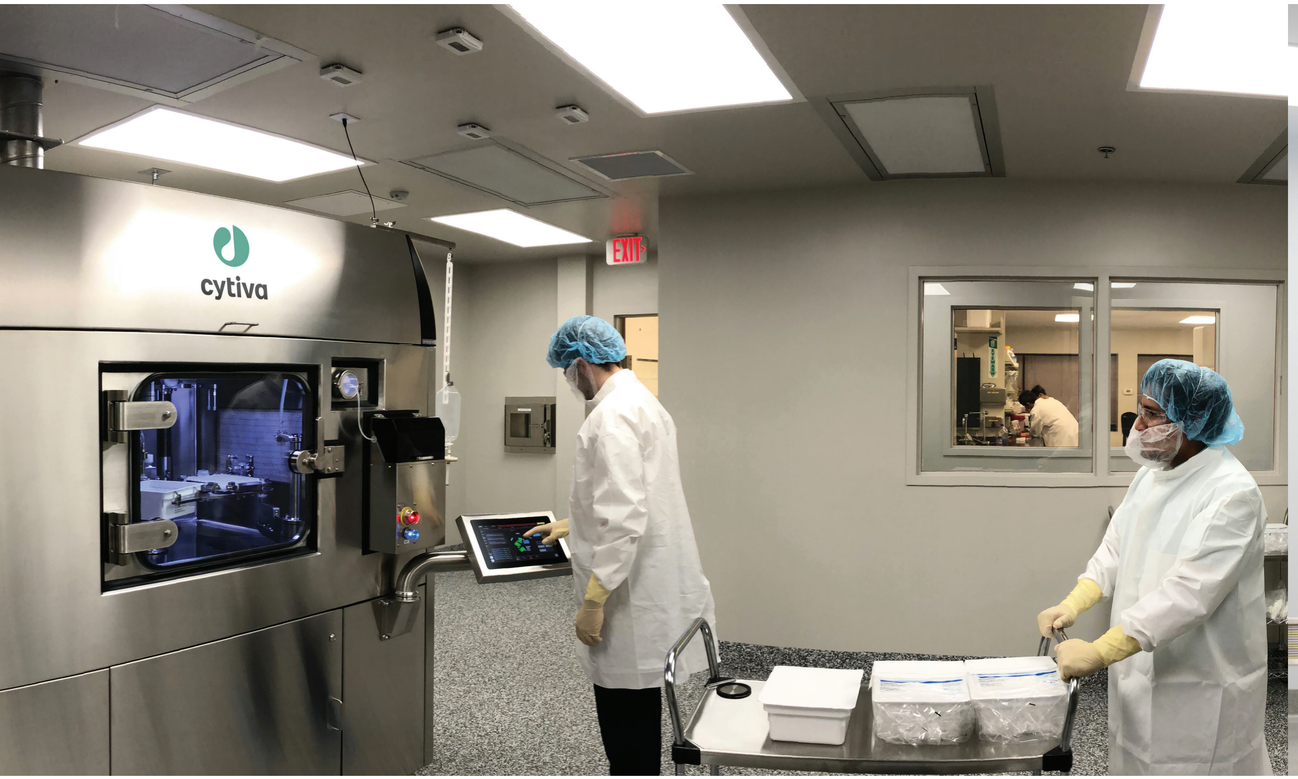
Moderna implemented the SA25 Aseptic Filling Workcell for drug development and clinical trial production of its mRNA drug pipeline at its Norwood, Massachusetts site. The machine was used to bring Moderna's COVID-19 vaccine candidates forward in only 66 days after the virus was sequenced.

Roche and Genentech

As Roche and Genentech focus on targeted therapies, the companies are transforming their manufacturing operations to meet future challenges — producing smaller batch sizes, increasing flexibility, and reducing human error. Cytiva SA25s and Microcells are now installed throughout their network. The companies chose our workcells based on their short lead times, low capital expenses, versatility in handling different container formats, and standalone utility requirements.

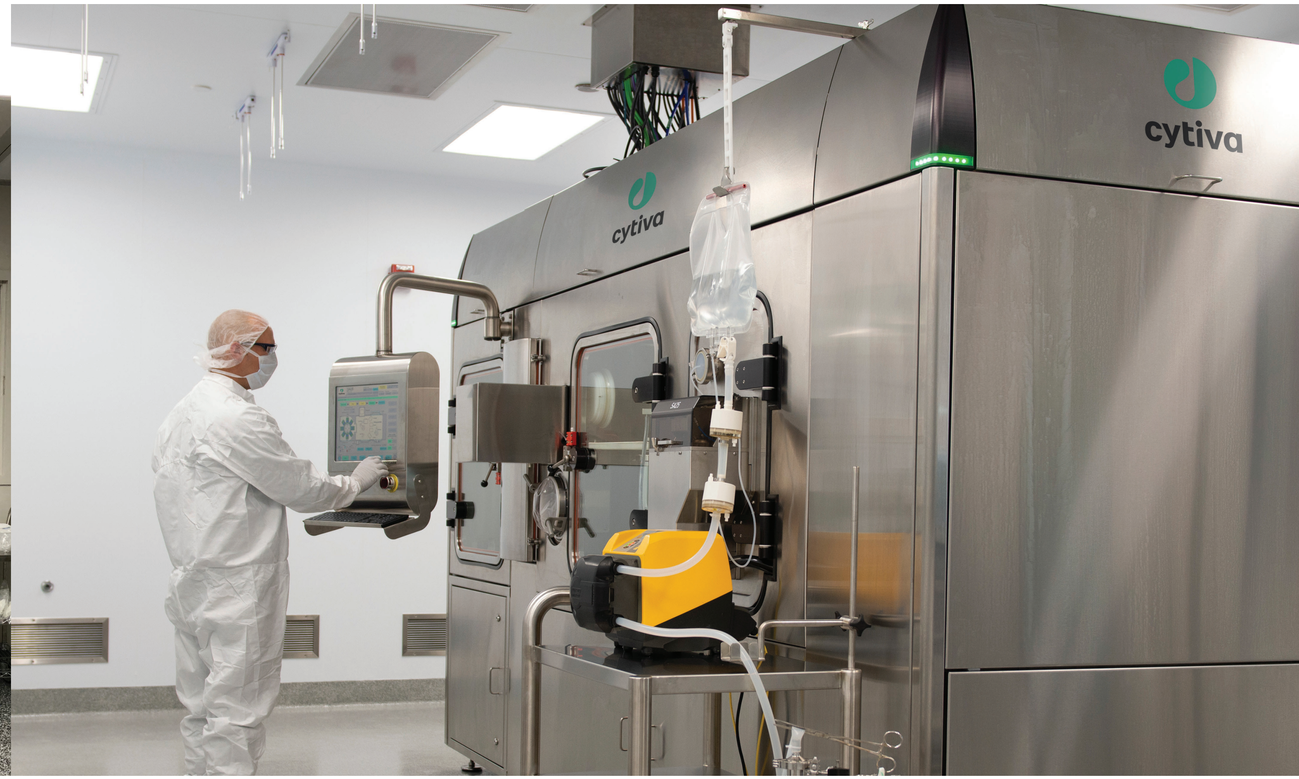
Microcell Vial Filler

The Microcell is used by Adaptive Phage Therapeutics, Roche, Genentech, Eurofins, and Locus Biosciences for the manufacturing of personalized medicines and early clinical trial materials.



SA25 Aseptic Filling Workcell

The SA25 is used for commercial and clinical manufacturing into vials, syringes and cartridges. Customers using the SA25 include Roche, Genentech, FUJIFILM Diosynth Biotechnologies, Amgen, Emergent BioSolutions, and Catalent.



Ready to take the next step?

Call us or visit our website to learn about production capacity, pricing, process videos, and more.

Phone: +1 604 453 8660

cytiva.com/aseptic-filling

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