

Take the lead on aseptic filling technology

Turn your manufacturing operations into an advantage



Fast. Flexible. Predictable.

Outdated manufacturing equipment shouldn't be the limiting factor in getting your drug product to patients when your science is so cutting-edge.

Whether your focus is cell or gene therapy, mRNA, antibody drug conjugates, or another novel therapy, you know that every step of the manufacturing process affects your ability to reach patients and meet your strategic and economic goals.

Cytiva Aseptic Filling Workcells are based on robotics and gloveless isolator technologies for an optimal aseptic process. The closed robotic systems bring flexibility to downstream manufacturing operations while reducing risk to patients, products, and corporate goals.

We've worked with top biopharma companies to bring manufacturing in line with their strategic and economic goals. Keep reading to learn how aseptic filling technology can help you reduce costs and get your products to patients faster.



What are the challenges of conventional filling technologies?

Process risk

Operator involvement in conventional technologies is a potential source of risk and error. We see the need for manual intervention as a design flaw in the aseptic process, as it introduces necessary risk of contamination.

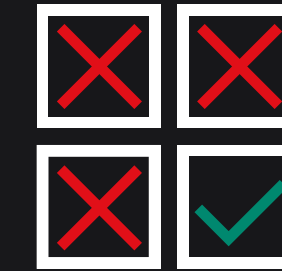
Custom = costly

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

Time consuming and slow

Conventional filling technologies have lead and implementation times of 2+ years. This affects your time to market and your bottom line.

We interviewed leaders like you to understand the pain points with their current aseptic filling solutions. Here's what they told us:



54%

Needed multiple iterations to get it right



46%

Dealt with delays



42%

Went over budget

78 people surveyed by The Linus Group in Q1 2020.



A conventional filling system with glove ports

How do our aseptic filling systems address these issues?

A closed system for reduced risk

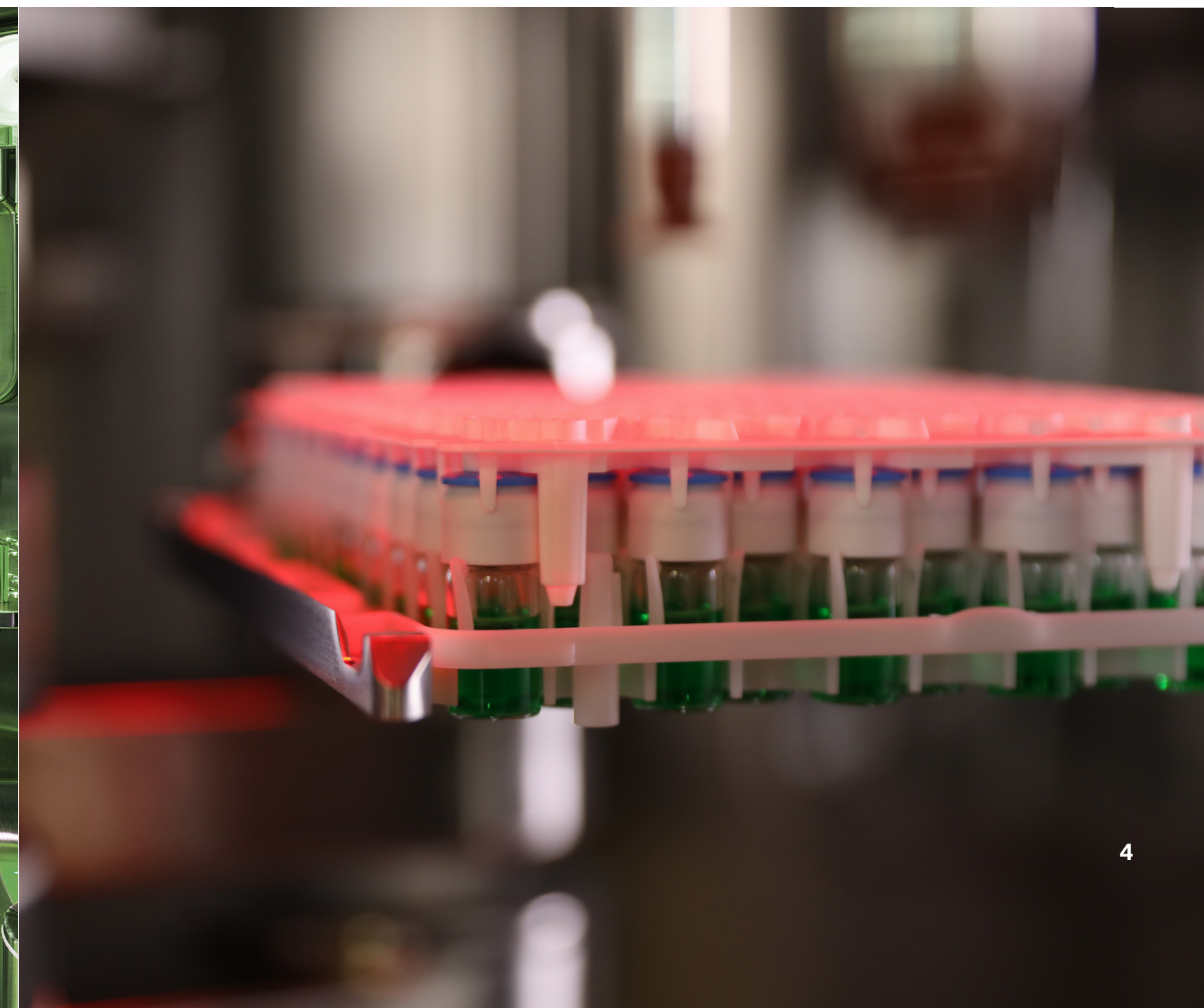
Our Aseptic Filling Workcells are designed to be completely closed systems. They do not have glove ports as operator intervention has been eliminated from the aseptic process. Advanced robotics drive repeatable processes for multiple dosage formats.

Standardized with built in flexibility

Our aseptic filling systems support a flexible aseptic process and multiple dosage formats. Standardization drives repeatable processes and getting 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 they choose. That means you can add machines quickly as candidates succeed in the clinic.



Economic impact

Save money on construction and supporting infrastructure

Our machines have a standard price through to the site acceptance test, including a standard validation package. The compact, integrated machine designs save space in Grade C clean rooms and have simple utility requirements.

Reach GMP faster

Help your company make and save money. Standardization with flexibility can reduce the timeline to GMP operations, so you can avoid the opportunity costs of being late to market. WuXi Biologics reached GMP with 7 different vial and syringe formats validated, just 15 months after its purchase order.

Reduce operating costs

Our Aseptic Filling Workcells support a high utilization rate with fast changeover and decontamination times to shift between drug products quickly and reduce downtime. The gloveless system also removes the need for operator intervention and reduces training costs.

From left to right: An SA25 occupies a small Grade C space compared to conventional filling machines; unifying the material handling method for multiple container formats enables flexibility and fast changeover; the Microcell provides a lower cost of entry into automated filling for early stage clinical materials or personalized medicines.



Strategic impact

Scale out strategies

With multiple manufacturing sites, coordination can be a challenge. Roche, Genentech, and WuXi Biologics have overcome this by adopting 'network' strategies and adding multiple aseptic filling systems to their operations. Therefore, they can cut tech transfer times with a repeatable production process.

Plan for change

As your products and formats change, so will your filling technology needs. With fully flexible, automated technology, you'll be ready to adapt.

Increase process control

Making a reliable, high-quality drug product is essential to your strategy. Standardization and automation increase control over the aseptic process and mitigate the chance of human error.



Top: a gloveless system means an operator is an observer of a closed process.

Bottom: the SA25's automated aseptic process enables process control and scale out to match your changing production needs.

**If you're not using
the Microcell
technology,
you're going to
fall behind in the
market.**

**Greg Merrill
CEO, Adaptive Phage Therapeutics (APT)**





From left to right: Adaptive Phage Therapeutics uses the Microcell in the creation of its PhageBank™ library of more than 1000 personalized drug products; ADMA Biologics integrated its supply chain for control over timelines and margins with the SA25; WuXi Biologics is scaling out with multiple SA25s after achieving success with its first SA25.

Adaptive Phage Therapeutics (APT)

APT is developing PhageBank™, a collection of viruses that target and kill bacteria, including highly dangerous multidrug-resistant pathogens. To meet the challenge of filling multiple viruses every day, the company needed a highly agile aseptic vial filling system. They chose the Microcell Vial Filler to accelerate the rapid filling operation and reduced a process that could have taken up to 10 years to a matter of months.

ADMA Biologics

ADMA Biologics is a biopharmaceutical company committed to developing and manufacturing plasma-derived immune globulin biologics for the prevention and treatment of infectious diseases in patients who are immunocompromised. Within a year of the purchase order for their SA25 Aseptic Filling Workcell, ADMA completed its site acceptance test, began in-house filling operations, and received FDA commercial approval in September, 2021.

WuXi Biologics

Global CDMO WuXi Biologics needed a system to fill vials, syringes, and cartridges with high quality assurance rates for clients. WuXi purchased an SA25 Aseptic Filling Workcell, and just 15 months later, reached its first GMP batch release. As of April 2020, WuXi Biologics is filling multiple container types for clients, with a quality acceptance rate of up to 99.5% of units. Several more standardized machines will be installed across their network in 2022.

Microcell Vial Filler

The Microcell is used by companies including 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 more about production capacity, pricing, process videos, and more.

Phone: +1 604 453 8660

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