

Build aseptic filling expertise

Optimize your drug product
manufacturing process



Fast. Flexible. Predictable.

Your drug products have the potential to change lives. Outdated manufacturing equipment shouldn't be the limiting factor in getting those products to market.

Whether your focus is cell or gene therapy, mRNA, or cytotoxics, you know how quickly the pharmaceutical industry is advancing. Like you, we understand that such rapid change demands flexibility in manufacturing, without compromising on product quality.

Cytiva Aseptic Filling Workcells are based on innovative technologies to help minimize risks in drug product manufacturing operations. The closed robotic systems bring flexibility to downstream operations while reducing risk to patients, products, and process.

We've worked with top biopharma companies to optimize their filling process for speed and quality. Read on to learn more about how we can help you streamline your operations.



What are the challenges of conventional filling technologies?

Inflexibility

Conventional aseptic filling systems need a day of downtime for cleaning, changeover, and decontamination after filling. This limits their flexibility to fill different drug products and multiple formats.

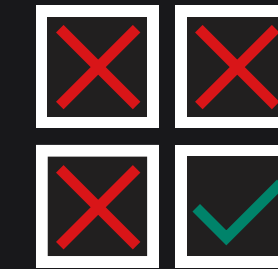
Limited scalability

Multiple change parts and wheeling modules in and out of cleanrooms complicates changeover and makes it difficult to scale drug production.

Long timelines

Until now, biopharma companies have had to customize their technology to meet the specifications of each project. This custom-designed equipment often takes 2+ years to build, install, and validate.

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

How do our aseptic filling systems address these issues?

Closed robotic workcells

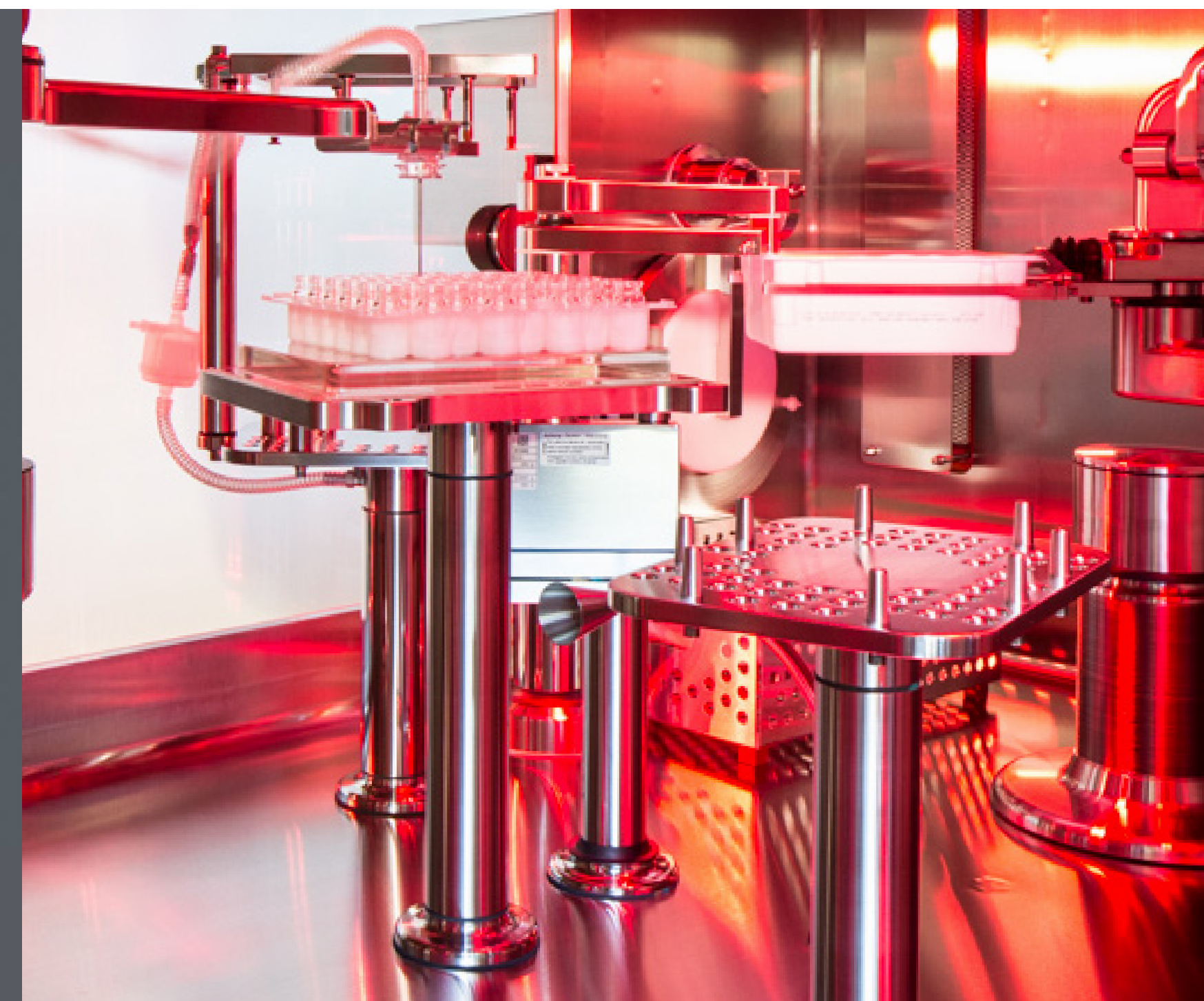
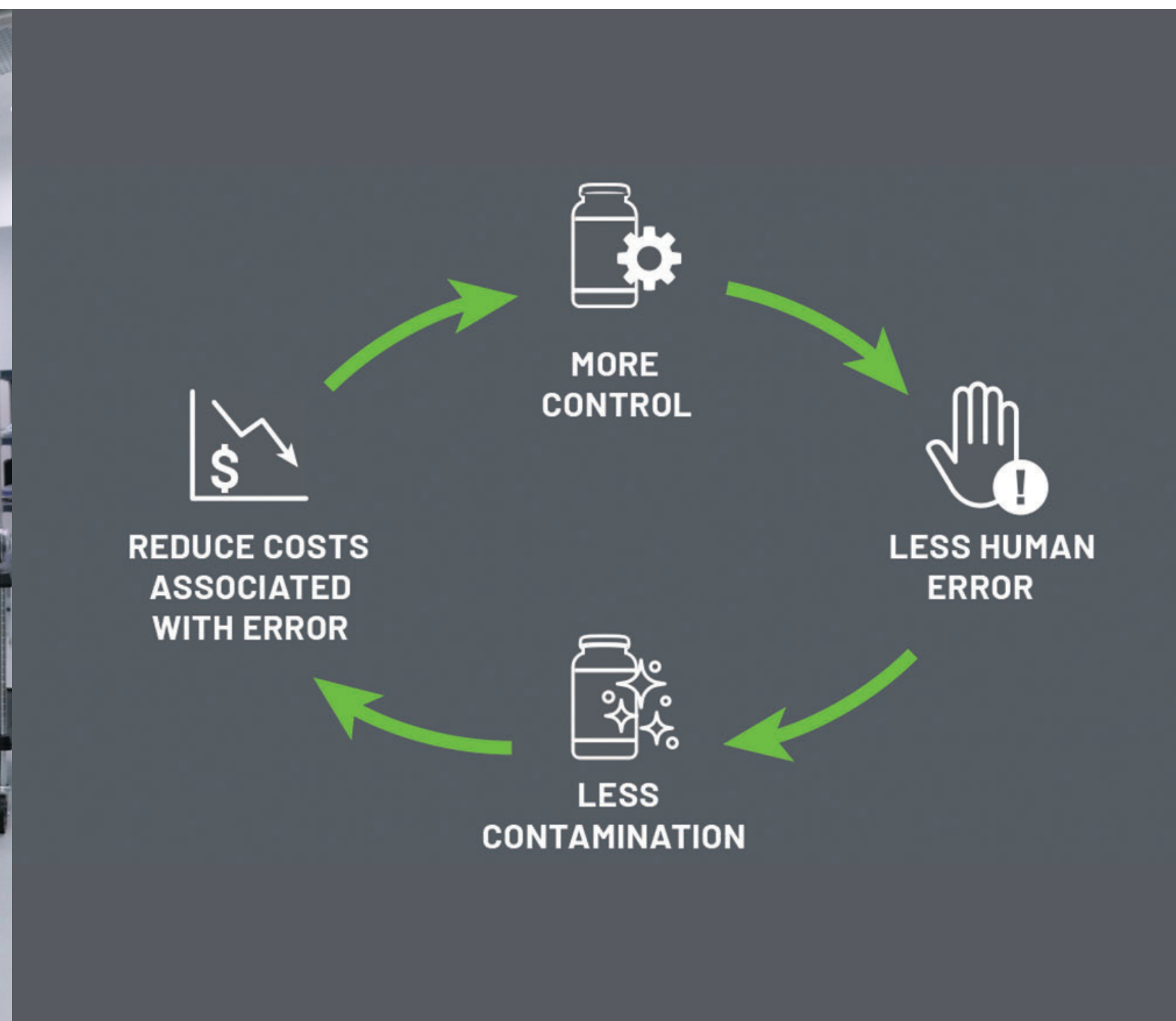
Our workcells use robotics in a closed aseptic environment to produce multiple drug formats repeatably and efficiently. Keeping humans out of the process reduces deviations, which also reduces risk to drug product quality.

A virtuous cycle

Advanced robotics help establish a “virtuous cycle” of automation and control. Fewer points of contact with an operator mean fewer chances for contamination. As the potential for costly errors or line loss decreases, your control increases.

Standardization for speed to patients

We build the same machine for every customer. Standardization means filling facilities can reach GMP in 6-15 months. Our Aseptic Filling Workcells allow you to quickly pivot between products or scale out production to meet the needs of your pipeline.



Operational impact

Go faster

Standardized systems help you simplify your construction project and eliminate the “design-by-committee” stage. Their small cleanroom footprints enable a ISO 7 or Grade C classification with simpler qualification and validation protocols.

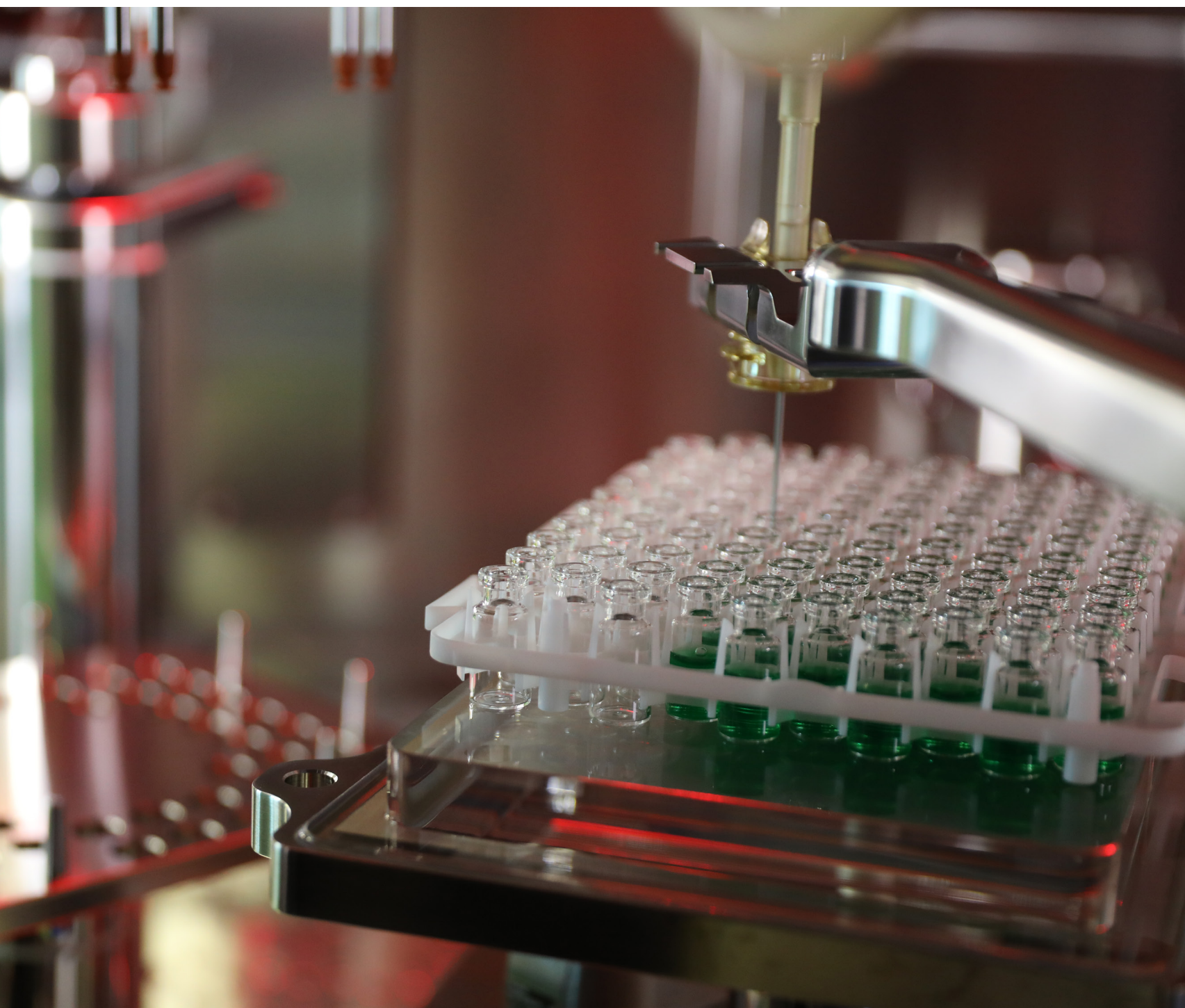
Remove variables

Without the conventional design flaws that put drug products at risk, our Aseptic Filling Workcells give you more control of your process. Advanced automation and robotics remove the need for operator intervention, and drug product contact is reduced to a single-use flow path.

Be flexible for the future

The future is uncertain – clinical outcomes, acquisitions, or in-licensing can mean significant changes in production requirements. Aseptic Filling Workcells are adaptable to these changes, including new dosage formats.

From left to right: The SA25 and Microcell use a single use flow path and filling needle to reduce contamination; An operator observes the filling process as it occurs robotically inside the Microcell Vial Filler; Multiple dosage formats can be filled on Cytiva Aseptic Filling Workcells, including vials, syringes and cartridges.



Production impact

Reduce risk

Aseptic Filling Workcells are gloveless isolators. With fewer points of operator intervention, you'll have fewer potential causes of contamination, line loss, or compromised drug product quality.

Streamline teams

Older technologies require teams of operators, but our workcells can be operated by a single person. Without a manual intervention step, training is more streamlined — each operator can focus instead on understanding the automation system and process. Robotics take care of handling, filling, and closing while your team focuses on other priorities.

Stay agile

Whether you're manufacturing high-value drugs or serving multiple clients as a CDMO, agility is everything. Rapid decontamination and aeration times under 1 hour make it possible to fill different drug products in different formats on different days — so when your production forecast or pipeline changes, you'll be ready for it.

Top: An operator using the touchscreen HMI to control the SA25 Aseptic Filling Workcell.
Bottom: Fully automated robots handle agile filling inside the Microcell Vial Filler.



A man with short brown hair, wearing a dark grey blazer over a light purple checkered shirt, stands in front of a blue building with white horizontal lines. He is smiling slightly and looking towards the camera. The background is a bright blue sky with some light clouds.

“The SA25 Aseptic Filling Workcell positions us well to manufacture next-generation therapies.”

Kevin Gadiant

Director of Manufacturing, Science and Technology, Emergent BioSolutions



From left to right: Singota Solutions produces clinical supply in vials, syringes and cartridges for its clients using the SA25; Emergent BioSolutions replaced a conventional filling line and has since gained commercial approval for products on its SA25; Roche and Genentech have installed multiple SA25s and Microcells as they introduce a new global standard across their network.

Singota Solutions

Singota Solutions is a CDMO based in Bloomington, Indiana that is focused on serving their customers faster. They recognized that companies developing drugs with smaller batch sizes were underserved by contract manufacturers. They needed an aseptic filling machine with fast lead and changeover times. For Singota, highlights of the SA25 Aseptic Filling Workcell include the repeatable robotic process and greater aseptic assurance.

Emergent BioSolutions

Emergent BioSolutions is a multinational biopharma company that manufactures protein therapeutics and contracted products. In 2016, their Winnipeg site determined that their existing aseptic filling system could no longer meet their production requirements or ensure regulatory compliance. The use of the SA25 has increased flexibility for aseptic filling and facilitated the transfer of FDA-approved commercial products without interrupting supply.

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. SA25s and Microcells are now installed throughout their network. The companies selected our Aseptic Filling 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.

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