The future of filling:

Addressing the challenges of late-stage manufacturing with aseptic filling solutions

At Cytiva, we've set out to create standardized aseptic filling technologies based on what's optimal for today's complex therapies—not yesterday's status quo. And to do that, we have to understand what defines optimal.

So we took snapshot of the current state of filling and late-stage manufacturing to discover where the risks and possibilities lie, and how we might reduce risk and optimize possibility (1). We spoke with 78 people working in leading biopharmaceutical, biotechnology, contract manufacturing, and cell and gene therapy or personalized medicine companies to learn about the needs, limitations, and risks they encounter producing the medicines of the future.

Here's what they told us.

Lofty goals meet limited technologies

The voices we heard come from three different work areas—filling operations and filling process engineering, manufacturing process development, and executive management.
But they share a common goal:

70% of respondents say "ensuring the safety of patients" is a top goal

56% of respondents chose "help improve patients' lives" as a top goal

Despite the complexities of navigating from the bench to the bedside, it's clear that today's biopharma leaders care deeply about serving patients, and that they want to do so as efficiently and safely as possible.

Late-stage manufacturing is a critical time for safety and efficiency. This is when the chemistry and process underpinning a drug product come under new scrutiny, and when decisions can affect scale-up and manufacturing for a long time to come.

It is when standardized and automated aseptic filling processes mean the most, ultimately increasing the value of a new medicine and its potential impact to patients.

Balancing need and risk

Whether they're working on process engineering, development, or at the executive level, scientists expressed a surprising insight: **that even though their science is unique, their aseptic filling needs aren't.**

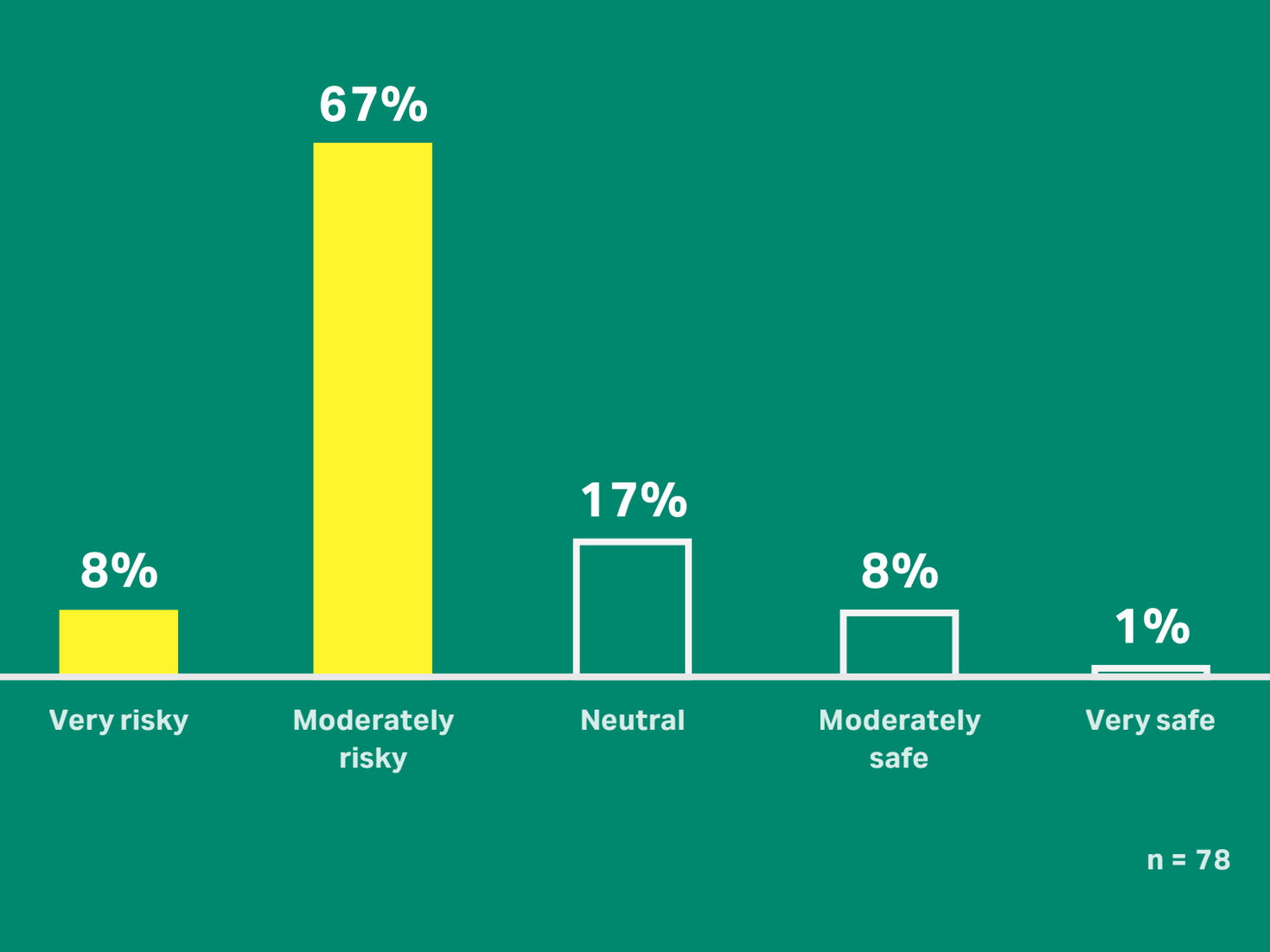
More than three out of four said that most companies in their industries had similar needs at the filling stage, regardless of specific differences in their drug products. Yet many find themselves building custom aseptic filling solutions anyway in order to overcome the limitations they face. And custom solutions come with certain challenges.

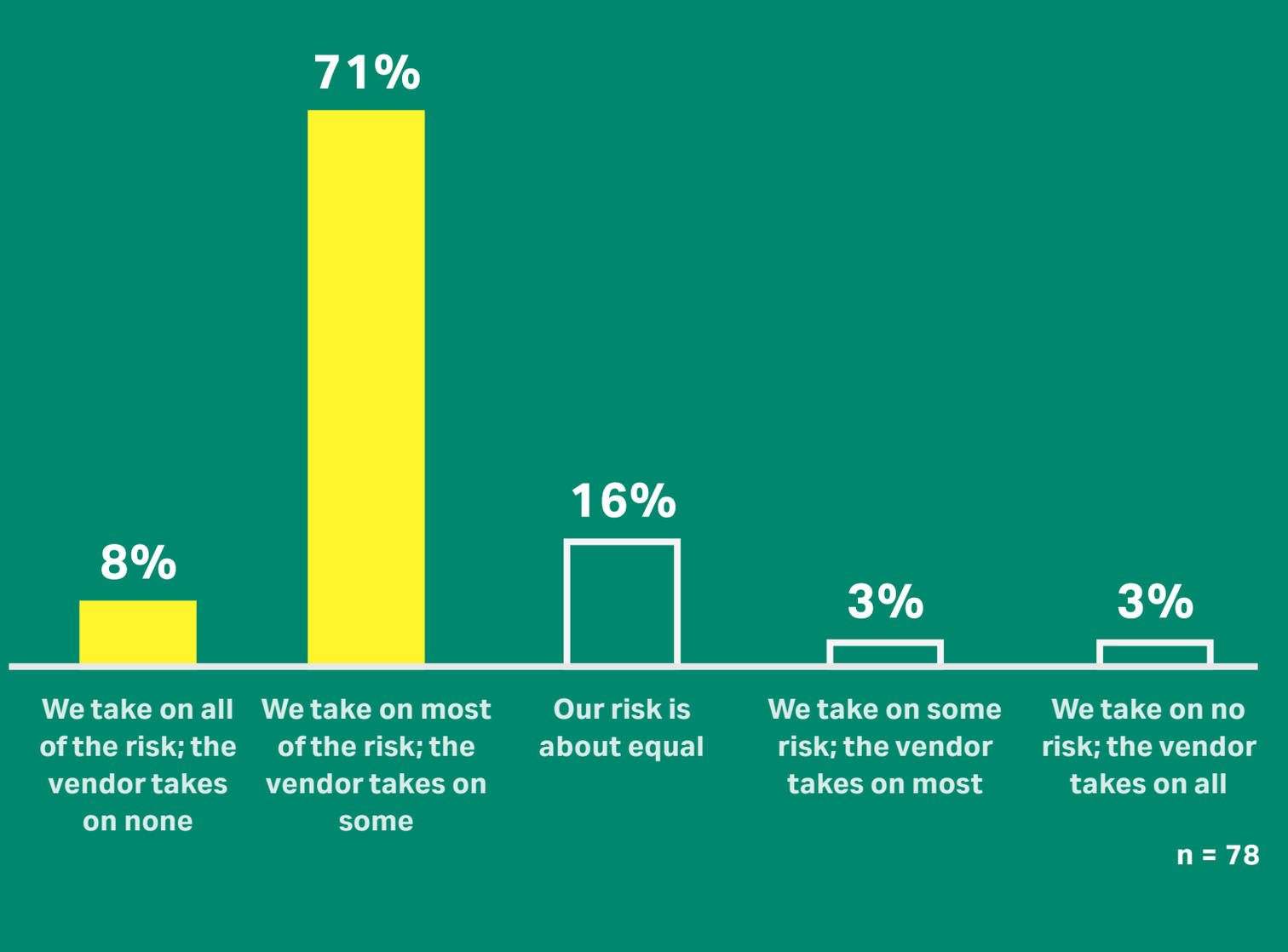
54% needed **multiple iterations** to get it right

46% dealt with **delays**

42% finished **over budget**

Greatest challenge is risk



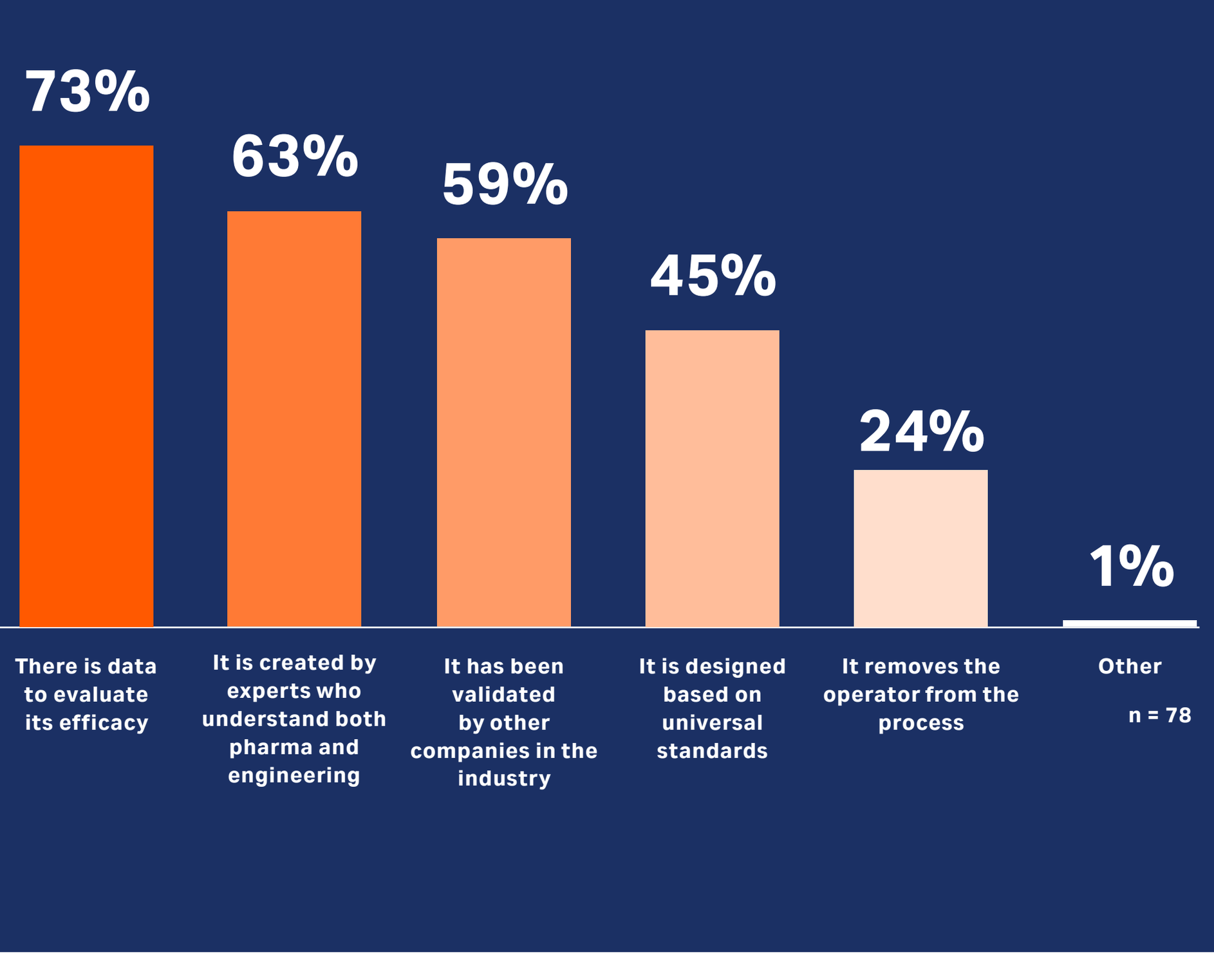


75% of respondents said it's **moderately or very risky** to develop and use a custom solution.

79% of respondents felt that the **burden of risk falls on their companies**, not the vendors building the custom technology.

> **Aseptic filling is a risky business, with significant uncertainties.**
>
> Pharmaceutical company executive

The majority are looking for a robust manufacturing technology solution that is **based on data, created by experts**, and **validated by other companies in their industry.**

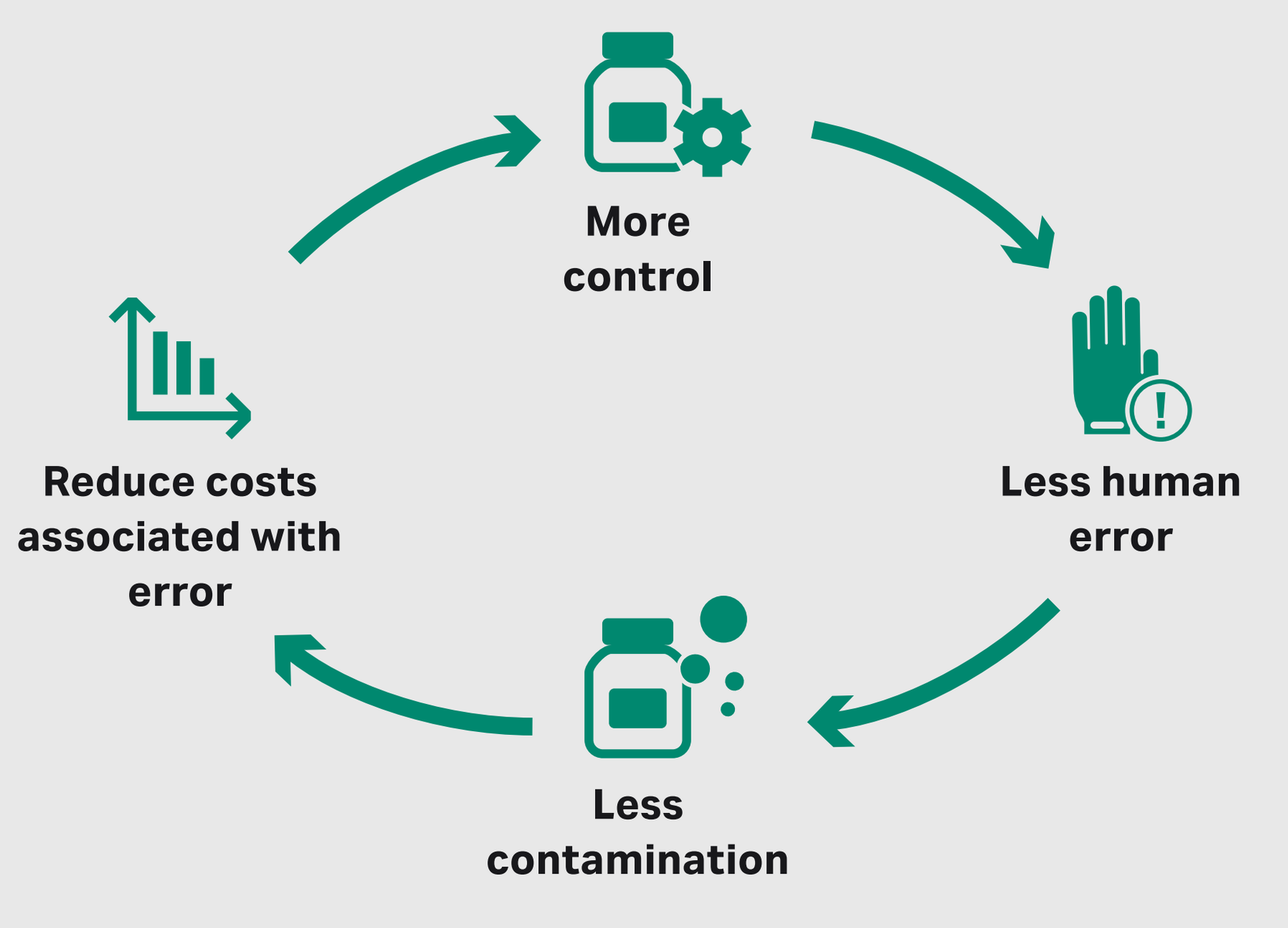


Standarization is the solution

Our respondents revealed two key ingredients for an optimal aseptic filling solution. One is **removing the complexities and costs** of a custom solution. The other is **removing the burden of risk.**

That means that a **standardized** solution that uses robotics and automation to increase control and reduce risk would enable the industry to move beyond today's limitations without compromise.

A standardized, optimized robotic solution creates what respondents described as a "virtuous cycle" of **higher control, less risk** of contamination and human error, **lower cost,** and **faster** time to market. Eighty-six percent of respondents found the idea of implementing such a cycle in their own companies appealing.



> **Using robotics to mitigate the chance for human error is always compelling.**
>
> Clinical stage biopharmaceutical company executive

Cytiva aseptic filling workcells make a virtuous cycle the new standard

We've drawn on our longstanding experience in the design, development, and fabrication of novel pharmaceutical manufacturing equipment, including robotics and automation systems, to create standard solutions for aseptic filling that **deliver greater control and speed while reducing risk**.

The fact that these systems are standardized means they can be validated — and they have been, by clients that include Adaptive Phage Therapeutics, ADMA Biologics, Emergent BioSolutions, FUJIFILM Diosynth Biotechnologies, and, Roche/Genentech.

> **Automatic filling should be the future.**
>
> CDMO manufacturing operations associate

Standardized, automated aseptic filling solutions are optimal. **And, they're here now.** Learn how Cytiva aseptic filling workcells can meet all your aseptic processing needs.

Find out about Cytiva aseptic filling solutions

References: 1. The Linus Group market awareness study on behalf of Cytiva, N = 78, unless otherwise stated. 2020.