# THE FUTURE OF FILLING:

## A look at the challenges and solutions for late-stage manufacturing

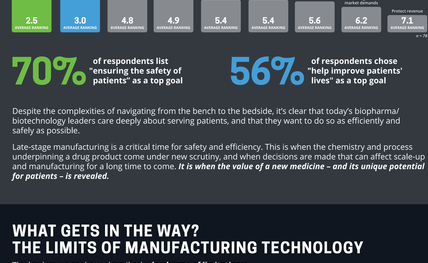
vanrx Pharmasystems Inc.

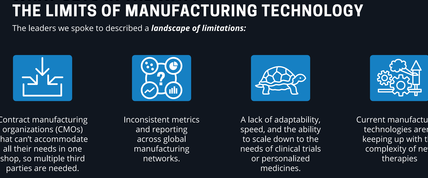
At Vanrx, we've set out to create standardized aseptic filling technologies based on what's optimal for today's complex therapies—not yesterday's status quo. And to do that, we have to understand what defines optimal.

So we took a 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. 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 have encountered as they work to produce 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 list "ensuring the safety of patients" as 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/biotechnology 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 are made that can affect scale-up and manufacturing for a long time to come. ***It is when the value of a new medicine – and its unique potential for patients – is revealed.***

## WHAT GETS IN THE WAY? THE LIMITS OF MANUFACTURING TECHNOLOGY

The leaders we spoke to described a ***landscape of limitations:***

Contract manufacturing organizations (CMOs) that can't accommodate all their needs in one shop, so multiple third parties are needed.

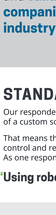
Inconsistent metrics and reporting across global manufacturing networks.

A lack of adaptability, speed, and the ability to scale down to the needs of clinical trials or personalized medicines.

Current manufacturing technologies aren't keeping up with the complexity of new therapies

## 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.***



**35%** Yes, most have very similar needs

**42%** Yes, most have somewhat similar needs

**15%** Neutral

**6%** No, most have somewhat unique needs

**1%** No, most have very unique needs

n = 78

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.

Fifty-four percent needed ***multiple iterations*** to get it right

Forty-six percent dealt with ***delays***

Forty-two percent finished ***over budget***

## THE GREATEST CHALLENGE, HOWEVER, 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*

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




## STANDARDIZATION IS THE SOLUTION

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

That means that a standardized – not custom – solution that uses robotics and automation to increase control and reduce risk would enable the industry to move beyond today's limitations without compromise. As one respondent, an executive with a clinical stage biopharmaceutical company, put it:

**"Using robotics to mitigate the chance for human error is always compelling."**

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.




**"Any innovation like this helps us stay state-of-the-art, which is what we want for, 1.) patients' safety, and 2.) regulatory compliance."**

*–Manufacturing Process Developer in Biotechnology*

## OUR GOAL AT VANRX IS TO MAKE THIS VIRTUOUS CYCLE THE NEW STANDARD

We've drawn on expert 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 solutions are standardized means they can be validated – and they have been, by clients that include Adaptive Phage Therapeutics, ADMA Biologics, Amgen, Emergent BioSolutions, FUJIFILM Diosynth Biotechnologies, and Roche / Genentech.

**"Automatic filling should be the future,"**

said a respondent in Manufacturing Operations at a CDMO. And we couldn't agree more. Standardized and automatic is optimal. It is the future. And it's here now.

Please visit **vanrx.com** to learn more.

vanrx Pharmasystems Inc.