Trusted partner for aseptic processing solutions

Reinventing your Aseptic Processing

WITH **FLEXIBLE ROBOTIC MANUFACTURING**

Overview

Today, new drug products and multi-product facilities demand higher precision and flexibility in aseptic fill-finish than ever before.

Targeted therapies require smaller batch sizes, and facilities must be able to quickly (and easily) pivot from one container format to another. As a result, today's market conditions require flexibility in processing, and heightened regulations drive the need for automation.

The future of aseptic fill-finish is flexible, highly automated equipment. With regards to traditional filling lines, robotic automation provides drug manufacturers with a higher degree of flexibility and accuracy than was previously possible. Simple, recipe-driven setup — and the ability to run entire batches without human intervention — significantly reduce the risk of process errors and contamination. These benefits have also been recognized by the FDA and other global regulatory agencies, thus leading them to highly encourage robotics to minimize human intervention within drug manufacturing.

In this e-book, we'll reveal:

- The most frequent fill-finish challenges
- Advantages of robotics in aseptic fill-finish
- How to prioritize quality and compliance

When it comes to biologic products, here are the most frequent fill-finish challenges that biotech manufacturers face:

1

UNCERTAINTY OF ULTIMATE PACKAGING CONFIGURATION (VIAL, SYRINGE, OR CARTRIDGE)

Negative implication of failing to overcome: Purchasing a fill-finish line that does not satisfy ultimate market needs

2

BATCH SIZES ARE BECOMING SMALLER AND SMALLER FOR PERSONALIZED MEDICINE

Negative implication of failing to overcome: Lines that do not support small batches have poor efficiency and poor yield of valuable drug substance

3

REGULATORY REQUIREMENTS ARE DRIVING TOWARDS AUTOMATION

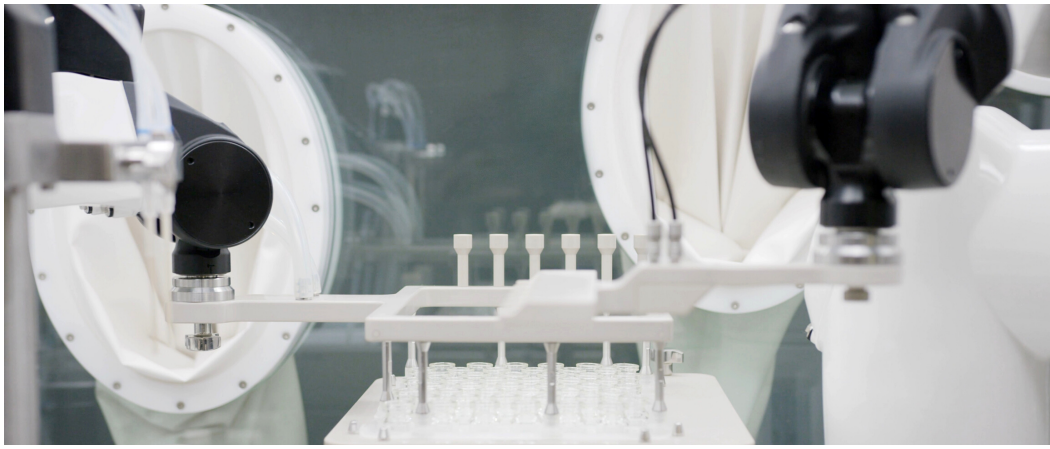
Negative implication of failing to overcome: Regulatory risk in future GMP audits of processes and equipment

4

RESPONDING TO SUPPLY CHAIN DISRUPTIONS BY HANDLING A WIDE RANGE OF PACKAGING COMPONENTS

Negative implication of failing to overcome: Risk in pausing production from being unable to accommodate alternative packaging in supply chain disruptions

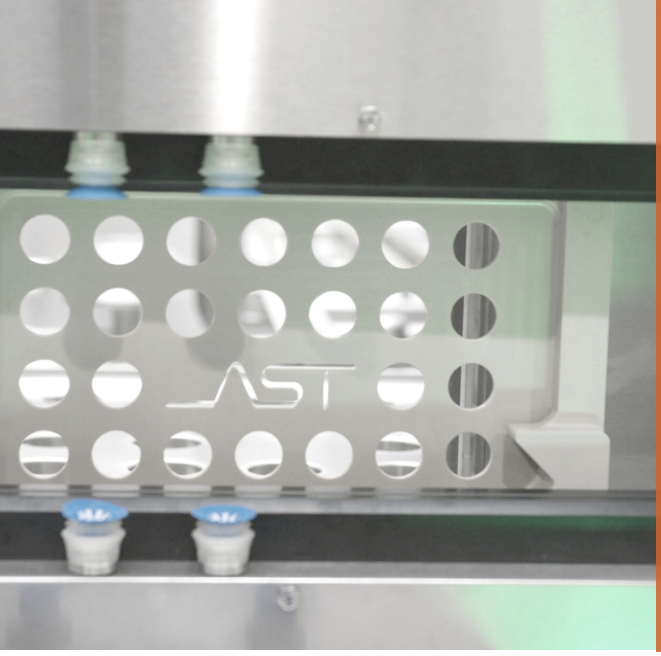


The Advantages of **Robotics**

IN **ASEPTIC FILL-FINISH** FOR COMPLEX BIOTECH MANUFACTURING PROCESSES

- Increased process precision, repeatability, and reliability
- Container format flexibility
- Smaller equipment footprint of flexible machines (vs. multiple single format lines)
- Minimizing human intervention
- High yield for small batches (batch size flexibility)
- Recipe-driven, fast line changeover



Quality & Compliance

AT THE FOREFRONT

Here's how to ensure you place quality and compliance at the forefront:

1

Make use of automation and robotics to reduce process variability. Recipe-driven robotic equipment is extremely precise and repeatable, ensuring that each container is filled exactly to specification.

2

Reduce regulatory exposure by following FDA guidance to implement automation and robotics. To minimize human intervention in filling processes, FDA guidance encourages the use of highly automated robotic machinery in aseptic fill-finish.

3

Integrate fill-finish lines with appropriate barrier systems, including isolators. Integrated barrier systems simplify decontamination, ensure that all systems are interacting as expected, and store all process data in a single location.

4

Utilize disposable fluid paths and high-precision pumps. Single-use fluid paths eliminate the risks of cross-contamination and improper pump cleaning. When used with highly precise pumps, product waste is kept to an absolute minimum.

About AST

AST's aseptic fill-finish systems satisfy the most challenging requirements for the Pharmaceutical and Biotechnology industries. Since 1965, AST has delivered innovative solutions including many industry firsts that have since become standard. AST's line of aseptic fill-finish systems provide solutions for every stage of drug development through commercial production. From semi-automated to fully robotic systems, each of our flexible products can process vials, syringes and cartridges on a single machine with simple change parts.

CONNECT WITH US

PRODUCED BY
GENERIS