Trusted partner for aseptic processing solutions

The Advantages Of Robotics In Aseptic Fill Finish

Innovations in drug development and manufacturing, as well as the technologies used to bring them to market, have led to exciting discoveries in patient treatment. For example, the ability to tailor therapies to the individual patient by using molecular and genomic drivers is bridging the gap between medicine and unmet clinical needs for rare and orphan diseases. Not only is this drastically changing the pipeline of many companies, but it is also leading to smaller batch sizes and more frequent recipe changeovers, profoundly impacting how drugs are produced. Manufacturers are looking for solutions to optimize operations to improve efficiency and reduce cost while enhancing quality.

In addition, modern drug development platforms must also be equipped to protect drug products from contamination by satisfying cGMP requirements for clinical and commercial sterile injectable products. This is especially applicable during the fill finish phase of biomanufacturing, as this is the last step before a drug product is delivered to the patient. As volume increases, recipe parameters and final containers vary considerably from batch to batch, forcing manufacturers to find a way to accommodate faster product changeover while still protecting sterility. One way to achieve this is by using robotic production lines that can provide flexible aseptic filling and closing of ready-to-use vials, syringes, and cartridges with a single machine, resulting in the overall production speed necessary to remain competitive and cost effective.

Added Flexibility And Product Protection

Failures during the aseptic fill finish process can result in lost batches due to contamination or drug product degradation that puts not only the efficacy of a drug at risk but also its safety. Small and emerging companies already facing a strain on capital often cannot afford these costly product losses during manufacturing or the inevitable delays that occur once an issue is discovered and investigated. In addition to cost, product losses threaten the ability to meet your supply needs. Drug shortages can delay clinical trials, preventing your product from reaching the market within the anticipated timeline.

Traditional production lines utilize multiple actuators in a complex arrangement because they are designed for maximum throughput. Conversely, robotic production lines are designed for maximum flexibility while maintaining relatively high aseptic processing rates. Product changeover in traditional systems can take one to two days to complete, which is especially burdensome due to the limitless number of setup configurations necessary to accommodate the wide array of specialized containers available today. In addition, traditional systems fill containers in a single line, requiring significant cleanroom space. A single aseptic robot can traverse a 3D space that would otherwise require many mechanical parts, allowing it to accomplish many jobs at once by moving to the different process stations instead of filling containers in line. This results in significant space savings and makes installing a new robotic system into an existing facility much simpler.

Robotic production lines address the needs of a shifting landscape by providing ultimate flexibility. A single machine can reliably produce many different products with minimal changeover time between batches. By using less parts, changeover of robotic systems is clean and low risk. Changeover is further simplified by recipe-driven programming, minimizing the parts required and leaving less room for human error. Instead of requiring physical adjustments and tool changes, recipes on robotic production lines can be selected and edited from the human machine interface and guided automatically by advanced vision systems. In addition, these features make introducing new container formats to an existing production facility much less burdensome. Robotic production lines allow new formats to be added to the machine quickly and easily without requiring significant mechanical changes to the machine itself.

Because robotic production lines call for a significantly lower total number of parts than traditional lines and are largely recipe driven, they are cleaner and lower risk. The features of a robotics production line also reduce the chance for operator setup and cleaning errors, which could ultimately cost the manufacturer an entire batch. Maintenance is simpler due to fewer parts and, if done properly, can result in significantly longer lifespans than the mechanical actuators of traditional lines. While robots in the past were not suitable for an aseptic environment, advancements in the design of today's aseptic robots make robotic production lines a reliable and clean alternative in aseptic fill finish. All parts of the robot are compatible with an aseptic environment and certified for use in aseptic operations.

By installing a robotic production line, manufacturers can adopt a footprint that is significantly smaller than a traditional production line, reducing both the initial investment in physical clean room space as well as operating costs down the road. A simpler line means replacing fewer consumables, simpler maintenance, decreased power consumption, and faster qualification and cleaning.

Introduce A Robotic Production Line Into Your Facility

The first step to implementing robotics into a production line is to identify the goals for your production line. Is this a new drug or an existing one that now needs to be filled differently? AST offers several different small

batch production lines with varying levels of automation to accommodate a wide range of customer needs throughout a drug's lifespan, including development, clinical trials, and even commercial production. All of AST's machines offer direct technology transfer between platforms, meaning that as your production needs increase, you can easily scale up to a larger AST platform.

After the machines are installed, AST offers training and aftermarket support. Systems can be equipped to process new formats at any time after installation, and technicians are available to make visits for service and support as needed. Robots facilitate ongoing maintenance by self-monitoring and using programmed alarm scenarios to alert operators of issues. These alarms appear on the human-machine interface and can often tell operators exactly what has gone wrong. When necessary, diagnostics can be performed remotely, allowing AST to begin an investigation immediately rather than waiting for someone to visit on-site. This type of intervention is facilitated by the simplified assembly of a robotic production line when compared to the complicated actuator assembly of mechanical parts.

Overall, flexibility is the antidote for uncertainty. As you move into a future of diverse pipelines that present both great opportunities and challenges, consider utilizing a solution like robotics that can be rapidly implemented into your facility. Not only does this give you the flexibility you need to adjust to future growth, but it also offers the speed to market necessary to be successful in today's changing industry.

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.

AST®

Trusted partner for aseptic processing solutions

We enhance the efficiency, productivity, and safety of flexible aseptic manufacturing processes for the worldwide life science industry by offering innovative products, services and solutions.

253-475-0200 sales@ast-inc.com www.ast-inc.com