

Robotic Aseptic Processing For Filling Ready-To-Use (RTU) Vials, Syringes and Cartridges



Fill-finish is the final stage before the product is packaged and administered to the patient. As patient treatments move away from broad population therapies in favor of the targeted treatment of smaller (personalized) patient populations, the biopharmaceutical industry is transitioning to smaller aseptic batch manufacturing processes.

It was not so long ago that robots were focused on end-of-line functions in the pharmaceutical industry, such as case packing and palletizing. Currently, robotic integration is gaining ground in the primary packaging processes for RTU containers, such as vials, syringes and cartridges. In RTU systems, packaging is pre-prepared so that the only step left in the process is to fill and finish the container, which eliminates the majority of process challenges.

Robotic solutions provide pharmaceutical manufacturers with a faster, more flexible and cost-effective way to fill different container formats using the same filling platform, responding to the growing demand for small batches, customized packaging, rapid product and format changeovers along with a less user intervention during the filling process. Conventional systems do not meet the need for small batch flexibility, multiple formats or sizes and repeatable processes that reduces risk.

Advances in technology have made robotics compatible with aseptic manufacturing, with near zero particle generation and complete tolerance to sterilizing agents. Robots offer one particular advantage over traditional aseptic machinery: flexibility. They are completely adaptable and can be reprogrammed with minimal investment if an application or container format changes.



Loading cell detail on the robotic filling

Robotic Filling Steps for RTU Containers

The syringes, vials, and cartridges are supplied ready-to-use already sterile and clean in a sealed nest/tub configuration; therefore no washing, sterilization, or special transportation is required. The nest with the empty containers is placed in an ISO standard tub, allowing for safe transportation and avoiding glass-to-glass contact. The user brings the nest/tub into their containment area (RABS/Isolator) where it can be automatically debagged and transferred to the next position. During the delidding process, the robot arm gently removes the pre-heated lid, the lid will exit through a mousehole in the baseplate of the restricted access barrier systems (RABS)/isolator chamber, into a waste container.

Only now are the containers in the nest exposed to the surrounding environment which is commonly within a RABs or isolator enclosure. Thereby minimizing the consequent risk of potential contamination. The robotic arm offers a safe and clean operation under the aseptic environment thanks to the RABS/ isolator, avoiding the potential contamination generated by human intervention during tub transfer and lid removal.



Delidding robot

Once the containers in the nest/tub are released from the top, it advances to the next step in which a second robotic arm transfers the nest with the empty containers to the filling position. During the filling process, the filling heads have a fixed position, and it is the robot that moves the nest and the containers to the filling position of each container, thus minimizing the generation of particles and the potential risk of contamination.



Nest pick and place to remove nest from the tub

Immediately after filling each container, the stoppering is carried out in a synchronized way by placing the appropriate closure element, in this way the exposure of the filled container to the environment is kept to a minimum.



Robot arm for cartridge filling

Once all the containers that make up the nest have been filled and stoppered, the robotic arm replaces the nest to its original position within the tub for the next technical process.

Robotic integration into the filling line process offers reliable repeatability of the movements while carefully manipulating the nest and vials, which is essential to reduce particle generation, air disturbance and unexpected vial shaking. This helps prevent spills and other incidents that would otherwise result in unplanned manual interventions, which could compromise the aseptic environment.

SP covers the complete range of aseptic processing tools and techniques, from cycle development, stability testing, pilot and clinical batch production through to full aseptic manufacturing and commercial production batches.

The SP i-Dositelco SY Syringe Filler is a versatile, robot filling and plunging/stoppering machine for glass and plastic syringes, cartridges and vials in nest. It can process up to 200 units per minute with a maximum of 10 nozzles. This system can incorporate an IPC statistic check weighing unit. In addition, complete line solutions with de-baggers, de-lidding, de-nesters, labelers and rod-inserters are available. The cleanroom style robot is used to position syringes for filling and stoppering, and available for VHP cleaning option.



For more product information on the SP robotic filling solutions, [click here](#)