# Flex-Line™ Robotic Filler for Filling RTU Vials, Syringes and Cartridges

ATS LIFE SCIENCES GROUP

**Author: John Erdner**
Portfolio Manager, Fill-Finish

Historically, aseptic fill finish lines typically had a washer and tunnel to wash and depyrogenate vials for injectable products. Usually, an aseptic filling line was dedicated to a particular component. In other words, there would be a line for vials and a separate line for syringes.

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. The move to smaller batch sizes created a market for lower line speeds, especially ones including freeze dried products, where the size of the freeze dryer is now smaller. Lower speed lines typically run more efficiently as they are more tolerant of component variability.

From the lower speed, mono component aseptic fill finish lines came the development of a single line that will do more than one component. This need drove ATS Scientific Products to develop the Flex-Line™ Robotic Filler which can process vials, syringes or cartridges on a single line using change parts to accommodate different configurations. For manufacturing sites that run small batch sizes or R&D departments developing new products, the idea of supporting a single filling line to produce a variety of products in multiple drug delivery forms is appealing from an investment, facility, staffing and maintenance perspective.

The market for prefilled syringes introduced the idea of pre-sterilizing components delivered to the aseptic filling suite in sealed presterilized tubs. Over the years, the process of delivering presterilized components expanded to include cartridges as well as vials. Presterilized components are more expensive than traditional raw glass but eliminate the need for washers and tunnels and are becoming popular for small batch and R&D applications.

The syringes, vials, and cartridges are supplied ready-to-use (RTU), 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 container-to-container contact. The tubs are then individually double bagged and shipped to the end user.

## Operations for de-bagging and de-lidding

The user brings the double bagged nest/tub into their containment area where the operator will sanitize the outside of the bag and open the first layer of protection, sliding the components with the inner bag into the de-bagging module. Within the RABs of the de-bagging module, the second bag can be manually, semi automatically or automatically debagged and by means of a no touch transfer, the tub will move to the de-lidding module.

During the de-lidding process, the robot arm gently removes the pre-heated lid. The lid will exit through a mousehole in the baseplate of the RABS or Isolator chamber, into a waste container.

Only now, are the containers in the nest exposed to the ISO-5 Class A environment which is commonly enclosed within a RABs or isolator containment. This minimizes 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.

Scientific Products offers many de-bagging and de-lidding options to match customer needs. We offer a semi-automatic or manual de bagging system to remove the outer bags and the de-lidding process can be a manual, semi-automatic or

automatic process using a robotic arm. The open tub will then automatically progress into the Flex-Line™ Robotic Filler under RABs or isolator. The isolator can also be customized for potent products if the application requires.

Environmental monitoring units are strategically placed relative to critical areas in both the de-lidding and filling modules to monitor viable and nonviable particles.

The Scientific Products Flex-Line™ Robotic Filler minimizes the distance between the opening of the ready-to-use (RTU) components and the filling and stoppering stations to reduce open component exposure to contamination particles regardless of the cleanliness of the environment. Even though the environment within the RABs or isolator have less than 100 particles (smaller than 0.5 µM) per cubic foot, it's advantageous to minimize the time the vial is open to mitigate risk of contamination.

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. Advances in technology have made robotics compatible with aseptic manufacturing, with near zero viable particle generation and excellent tolerance to sterilizing agents. Robots offer one advantage over traditional aseptic machinery: flexibility. They are versatile and can be reprogrammed through HMI recipe selection with minimal investment when an application or container format changes.

Robotic solutions provide pharmaceutical manufacturers with a faster, more flexible, and cost-effective way to fill different container formats using the same filling platform. Robots can adapt to customized packaging, rapid product and format changeovers with less user intervention.

The use of robotics to replace human intervention is also a huge advantage from a risk perspective. Fully gowned operators can give off 30,000 colony forming units per hour so using robots greatly reduce the risk of contamination. The Scientific Products Flex-Line™ Robotic Filler offers robotic solutions to manipulate the components to the de-nesting, filling, stoppering, weigh check and re-nesting operations to reduce the risk of product contamination.

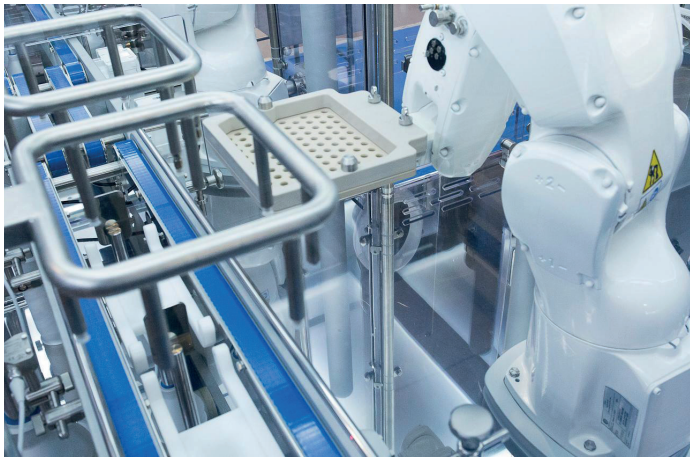
## Flex-Line™ Robotic Filler versatility

The Scientific Products Robotic Flex-Filler™ is a versatile, robot filling and plungering/stoppering machine for glass and polymer syringes, cartridges and vials in nest. It can fill 1, 2, 5 or 10 components at a time, processing from 15 to 200 units per minute (upm). This system can incorporate 100% check weighing capability or an IPC statistical check weighing. In addition, complete line solutions with the aforementioned de-baggers, de-lidding, solutions for upstream RTU components can also seamlessly connect with downstream de-nesters, labelers and rod-inserters for syringes and freeze dryers with loading systems, cappers, external vial washers and tray loaders for vial applications.

## Operations within the Flex-Line™ Robotic Filler

The overall functionality of the machine is the same regardless of the quantity of filling stations and number of components handled simultaneously.

Once the containers in the nest/tub are released from the tub, 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 potential risk of contamination



The standard filling solution is by peristaltic pumps. However, depending on the product need, we also offer positive displacement pumps, vacuum filling as well as special filling systems for viscous products.


Immediately after filling, each container is stoppered. The standard stoppering method is a mechanical placement of the stopper within the container to a precise level. As an option we also offer vacuum stoppering.

Check weighing to verify dosage can be either 100% or statistical.


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 or connection with downstream equipment.

## ATS Life Science Group offers a total solution for one-stop shopping

Scientific Products, as part of the ATS family, now allows us to offer an isolated turnkey solution for the entire line. Offering an integrated FAT and seamless installation, SAT, and qualification support for both the processing equipment as well as the isolators.

As one family, we offer short deliveries for many full line solutions including the Flex-Line™ Robotic Filler.

Scientific Products also offers a 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 for freeze-drying products.

Our line-of-sight tools are best in industry to support product development and get customers to market first with a high quality consistent product.

Check our website for all ATS LS Group, Scientific Products and Comecer offerings or call your direct salesperson for an appointment.

***Flex-Line™ Robotic Filler Automation***

***Flex-Line™ Robotic Filler Automation with Isolator***

***Flex-Line™ Robotic Filler Automation with RABS***