# **ApiJect<sup>™</sup> Technology Development Center**

ApiJect is a U.S.-based, medical technology company using Blow-Fill-Seal (BFS) manufacturing to revolutionize how the world fills, finishes, and delivers injectable pharmaceutical drugs and sterile liquids.

ApiJect has recently completed the construction of its Technology Development Center in the greater Orlando, Florida-area. The ApiJect Center is focused on helping pharmaceutical companies prepare their drug product for high-speed, high-volume



production in a new type of scalable prefilled syringe that is made largely using the Blow-Fill-Seal aseptic process. The ApiJect Center directly supports the future installation of large-scale commercial manufacturing for rapid deployment of critical medications.

## **Expertise and Machinery**

#### **Our Experienced Industry Leaders**

- In-house expertise in BFS manufacturing and device design/engineering with the ability to rapidly provide proof-of-concept and small-scale manufacturing.
- BFS experts, device engineers, computer numerical control (CNC) machinists, and scientists, each with at least 15 years of field-related experience.

#### **Our Best-in-Class Machines and Utilities**

- Machine shop with Hurco<sup>®</sup> 3-axis milling machines for prototype BFS mold design and production.
- Weiler Lab+ BFS machine for small-scale BFS evaluations (<5,000 container trials).
- Rommelag<sup>®</sup> 434 BFS machine for medium scale BFS evaluations (>5,000 container trials).



Weiler ASEP-TECH® Lab+

Rommelag® 434

 Full site integration of utilities for BFS manufacturing including dedicated clean steam generation, purified water systems, compressed air, chilled water supply, and cold processing capabilities.

## **Planned Future Expansion**

The ApiJect Technology Development Center is projected to expand from its existing 16,000 square feet footprint over the next year to a 32,000 square feet freestanding facility accommodating four BFS lines, inspection, and packaging, as well as ancillary infrastructure for device prototyping and development through U.S. FDA Current Good Manufacturing Practice (cGMP) compliant commercial scale fill-finish and production. ApiJect completed this initial phase of design and construction of 16,000 square feet within 8.5 months. Architectural and engineering work for the second phase is planned for 2022, with initial construction targeted for Q3-2022.

### About Blow-Fill-Seal (BFS)

BFS is an industry-recognized advanced aseptic liquid drug packaging process. In about 3-8 seconds, a rotary BFS machine forms a plastic container, fills it with a dose of the drug, and sterility seals the top. BFS is a highly efficient and scalable process, with a single larger BFS machine able to fill-finish up to 15 million doses a month.



The polymer parison is extruded from granulated resin and positioned inside the open mold.

Extruding

Blowing The mold closes and, in doing so, welds the base. Sterile air is blown into the parison to create the desired shape.

The exact amount of filling as measured by the dosing system is fed into the container via the mandrel.

Filling

Sealing

Once the mandrel is removed, the head mold comes together to form the desired closure type. Demolding

Opening the mold releases the container from the system and the next cycle begins.

## About ApiJect's Technology and Platform

ApiJect has invented a scalable and efficient drug delivery platform that enables attachable plastic components, such as a pen needle-style hub, to be attached to the top of the BFS container, turning it into a new type of single-dose prefilled syringe. The results are seen in our first potential device, the 0.5mL \*. By twisting the Needle Hub onto the BFS Container and removing the cap, the healthcare worker can then inject the medicine into the patient by squeezing on the soft plastic container.

