

Apiject Systems Announces the Opening of the Apiject Technology Development Center in Greater Orlando, FL

New Facility Brings to the U.S. Critical Capabilities for the Design, Engineering and Testing of Apiject's High Volume Manufacturing Process for Making Single-Dose, Prefilled Syringes.

Stamford, CT., April 13, 2022 — Apiject Systems, Corp., a medical technology public-benefit corporation that will transform how injectable vaccines and medicines are filled, finished, and delivered, announced today the launch of the Apiject Technology Development Center in greater Orlando, FL.

This new facility is devoted to working with pharmaceutical companies to design, engineer and test how to fill and finish their injectable drug products in a new type of scalable, single-dose prefilled injector that is made using the Apiject Platform. By bringing together the high-speed, high-volume Blow-Fill-Seal (BFS) manufacturing process with attachable components, including Needle Hubs, the Apiject Platform is designed to make it possible for more injectable medicines and vaccines to efficiently be filled and delivered to patients in a prefilled injection device. This facility provides capabilities to shorten supply chains and bring the development of critical injection device technologies back to the U.S.

With the public-private partnership support of the U.S. Department of Health and Human Services – Office of the Assistant Secretary for Preparedness and Response (ASPR), and the U.S. Department of Defense, the Apiject Technology Development Center (the Apiject Center, for short) brings to the U.S. critical capabilities for device design, engineering, testing, BFS mold development, and small-scale manufacturing of single-dose, prefilled injectors and other parenteral devices under one roof. The Apiject Center also enables the fill-finish of smaller batch sizes for feasibility testing and device use testing, leading to commercial development.

Apiject Chief Executive Officer Jay Walker commented: “The Apiject Center is where the future of injection technology will be created. The Center adds a critical development capability that supports Apiject’s existing fill-finish lines at our manufacturing partner site in South Carolina, which currently has the capacity to produce up to 540 million single-dose prefilled injectors annually. Together, these facilities expand the domestic pharmaceutical supply chain and catalyze our ability here in the U.S. to respond to key public health issues such as syringe shortages, syringe safety, and the critical need for surge fill-finish capacity not only for this pandemic worldwide, but also for future pandemics and bio-emergencies.”

Mr. Walker continued: “There has been much discussion in recent years, rightly focused in my judgment, about the need to shorten supply chains and have critical technology here in the U.S. Our partners in the U.S. Government have strongly emphasized this priority from the pandemic’s very beginning. The Apiject Center has been created to serve just such a purpose. Its current footprint of 16,000 sq. feet is just a start. Over the next year, the Apiject Center will double in size. The current BFS machines will be supplemented by an additional two machines. The Apiject Center, here in Central Florida, will be launchpad for the future of injectable device technology.”

“Strengthening our nation’s health supply chain and expanding domestic manufacturing capacity are

key priorities for ASPR,” said Assistant Secretary for Preparedness and Response Dawn O’Connell. “We are pleased to support ApiJect’s efforts to develop new and innovative approaches to how injectable vaccines and medicines are filled, finished, and delivered so that the nation is prepared for future pandemics and health emergencies.”

The ApiJect Technology Development Center is made possible in part thanks to \$9.6 million in funding from the HHS Office of the Assistant Secretary for Preparedness and Response. ASPR leads the federal government's health care and public health preparedness, response, and recovery efforts.

Bob Ward, President and CEO, Florida Council of 100, a not-for-profit organization of Presidents and CEOs, commented: “We are excited to welcome ApiJect as another great example of a medical technology company expanding the health innovation sector in Florida. ApiJect is exactly the kind of company that builds a strong economic future for our state and its citizens.”

ApiJect completed the ApiJect Center’s initial phase of design and construction within 9 months and on budget. When fully built out, The ApiJect Center will contain infrastructure for device prototyping and development through U.S. FDA Current Good Manufacturing Practice (cGMP) compliant commercial scale fill-finish and production.

The first potential device made on the ApiJect Platform is the Prefilled ApiJect Injector, a single-dose prefilled injector designed to efficiently deliver a 0.5mL dose into a patient with a simple squeeze of the BFS container by the health professional. This new type of prefilled syringe will be ApiJect’s first product submitted for regulatory review and approval. The Prefilled ApiJect Injector and its manufacturing process include:

- An aseptically filled single-dose container, designed to enable efficient and intuitive injection administration.
- Pen needle-style hub (including a patented connector for BFS container interface and Needle Hub mounting).
- Innovations in temperature management to expand the range of medicines and vaccines suitable for BFS packaging.

The ApiJect Center’s team includes BFS experts, device engineers, machinists, and scientists, each with years of field-related experience. The team will provide ApiJect with the capability to provide process and product proof-of-concept and small-scale manufacturing supporting commercial development. For a fuller description of Best-in-Class Services and the technology supporting them, please click the following link: https://apiject.com/wp-content/uploads/2022/04/70820_Data-Sheet-only_3.pdf.

About ApiJect Systems

ApiJect Systems, Corp. is a public-benefit medical technology company working to use our platform to bring more prefilled, single-dose injections to patients everywhere. The ApiJect Platform enables pharmaceutical and biotech companies to design scalable prefilled injectors and efficiently fill-finish them with their injectable drug products. This can be done either on one of their own ApiJect-licensed Blow-Fill-Seal packaging lines or at one of our world-class manufacturing partners.

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