

# MED TECH

*OUTLOOK*

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2023

**ApiJect Systems, Corp.**

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# ApiJect Systems, Corp.

## Revolutionizing Prefilled Syringes with Blow-Fill-Seal Technology

As the market for parenteral drugs continues to grow, more companies are looking for solutions that deliver the benefits of prefilled formats but with greater manufacturing efficiencies. Medical technology company, ApiJect has designed the perfect solution for that. It combines the competencies of aseptic blow-fill-seal (BFS) drug packaging technology with plastic injection molded components to create single-dose, high-quality, prefilled drug delivery systems, subject to FDA approval.

ApiJect is driven to improve how sterile liquid medicines and vaccines are fill-finished to help pharmaceutical companies design drug delivery systems cost-effectively and at scale, with a goal to help make injectable medicines and vaccines safe and accessible for everyone.

Bringing pharma companies, contract manufacturers, and healthcare providers one step closer to that goal is the ApiJect Platform. It is the brainchild of Marc Koska, OBE, co-founder and head of product design of ApiJect, who leveraged decades of experience in auto-disable syringes to develop and perfect the solution. It enables injectable drugs to be filled and finished as one continuous process.

In addition, the first potential device made on the ApiJect Platform is a compact, prefilled, single-dose soft syringe designed to scale quickly and efficiently. ApiJect is also making advancements in BFS temperature management so that a wider variety of temperature-sensitive, sterile injectable drugs, including mRNA vaccines, can take advantage of BFS.

The ApiJect Platform, with potential fill volumes between 0.25ml and 5.0ml and beyond, is designed to serve a wide range of parenterals injection routes; intramuscular, subcutaneous, intradermal, and intravenous, as well as traditional BFS routes like oral, optic, and inhalation.

### Simplicity at its Core

Its Prefilled ApiJect Injector drug delivery system is designed to combine BFS technology and a pen needle-style needle hub. The device is designed keeping its ease of use in mind; just before administering an injection, all a healthcare professional would need to do is push together a prefilled BFS container and intramuscular needle hub to



create a ready-to-use drug delivery device. This attachment causes the needle to pierce the BFS container, activating the device. The liquid drug product can then be expelled by squeezing the BFS container. Its simple-to-use injection system is designed to make it a user-friendly product for both healthcare professionals and patients, where allowed by regulators.

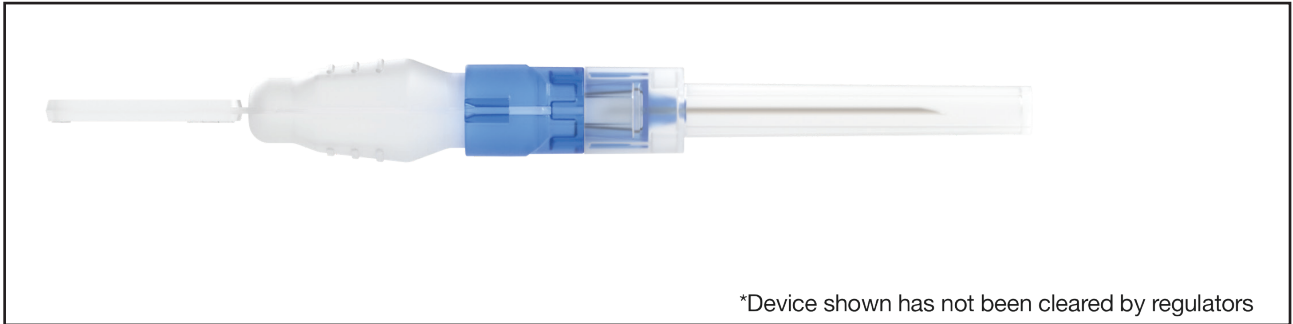
As a single-use, prefilled format, the Prefilled ApiJect Injector is designed to reduce dosing errors and help prevent needle reuse. And since they are designed as an efficient, reliable, and convenient method for drug administration, ApiJect devices have the potential to minimize drug wastage.

## Expanding Capabilities with Plain Sailing Manufacturing

In the BFS process, containers are rapidly formed from plastic resin, filled with sterile liquid medication, and sealed in one continuous motion. These containers can be formed into different shapes, have different fill volumes, and have different connector assemblies that allow various types of needles or other elements (like oral, nasal, or eyedrops) to be easily attached to them.

High heat affects certain biologics and can impact their shelf life. ApiJect has developed temperature management technology to serve active pharmaceutical ingredients (APIs) that require temperature limits. Its sophisticated and precise temperature control mechanism in the system may enable a broader range of content to be filled in BFS and cater to various customers.

To bring high-speed, high-volume, and fill-finish capacity domestically to France, ApiJect is collaborating with the



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“We also have the capability to design and create customized drug delivery components, including needle hubs, which can be easily and securely attached to a client’s prefilled BFS container,” says Koska.

Compared to glass vials and syringes, Prefilled ApiJect Injectors have fewer parts, no glass, and employ an intuitive design to help lessen these inconveniences.

“Our one continuous BFS operation in manufacturing leads to fewer components and is a step toward addressing drug delivery challenges and offering a cost-efficient drug delivery system,” says Jon Ellenthal, president of ApiJect.

Since the plastic in the ApiJect Prefilled Injector is sterilized during the extrusion process, no further sterilization is typically used. In addition, the lack of glass can reduce the risk of particulate contamination and accidental breakage. These potential efficiencies make ApiJect devices an apt solution for drug delivery.

French pharmaceutical company Fareva. They have entered a 10-year licensing agreement to use ApiJect technology to manufacture single-dose prefilled injections. Fareva plans to use ApiJect’s cutting-edge prefilled injector technology when operational to fill and complete more than 500 million doses of vaccines and other large-molecule injectable medications each year.

## Taking Global Injectable Market One-Step Further

ApiJect devices under development are designed to be easy to scale. A single high-end BFS machine can produce up to 150 million units of finished goods every year. This manufacturing process is ideal for emergencies due to its simple supply chain and massive production capacity. For example, during the initial response to COVID-19, ApiJect worked with the U.S. government to increase manufacturing capacity to meet the emergency response challenge.

ApiJect’s founders see this manufacturing scale as essential to address global health market needs. “To tackle the challenges arising from syringe reuse around the world, we are focused on enhancing our ability to improve the safety of the administration of vaccines and other injectables in global health markets,” says Jay Walker, co-founder, executive chairperson, and CEO of ApiJect.

Regardless of manufacturing volume, ApiJect, with its roots embedded in global health, aims to make injectable medicines and vaccines safe and accessible to everyone in all markets with its advanced technology. [LMT](#)