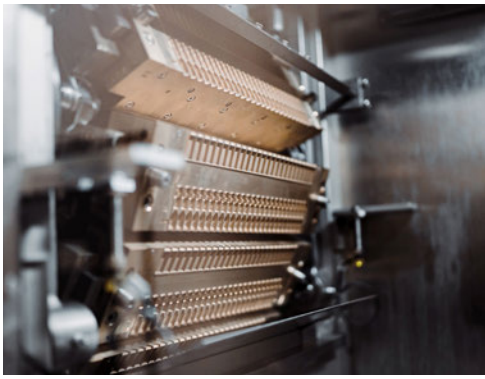
apiject™

Blow-Fill-Seal

KEY BENEFITS OF BFS

- **Sterility Assurance**
  Advanced aseptic processing that forms, fills, seals in a contained ISO 5 area with minimal human intervention
- **Serves Small and Large Batches**
  BFS can efficiently handle batch runs ranging from small to very large with consistently high-quality
- **Wide Range of Drug Products**
  ApiJect temperature management technology enables BFS to serve a growing range of biologics and other liquid products
- **Compact Supply Chain**
  Formulation to secondary packaging in one tight process train with a small footprint and cost-effective process
- **Robust Surge Capacity**
  Rapidly adjustable to meet high volume requirements to meet both high and low volume requirements
- **Customization**
  The flexibility of polymer allows you to shape for brand or product customization capable of serving many markets from saline to liquid vaccines

ADVANCED ASEPTIC FILL-FINISH PROCESS



At the center of our design and technical solutions is Blow-Fill-Seal (BFS) rotary machines. Blow-Fill-Seal, is an industry-recognized advanced aseptic fill-finish process. The filling chamber during the BFS process is isolated in an ISO-5 environment, and the efficiency of BFS allows for manufacturing campaigns to be fulfilled with reliable quality regardless of container size or volume. Since BFS uses polymer containers, the respective drug delivery system can be offered in various fill volumes and container shapes, with minimal changeover time.

BFS AS A SOLUTION FOR COMPLEX FORMULATIONS

BFS aseptic filling technology enables a wide range of liquid pharmaceutical products to be successfully produced, including simple saline solutions, small molecules, and more complex products like emulsions, suspensions, and heat-sensitive products such as biologics and vaccines. When considering BFS packaging for your drug, our experts will work with your team to fill it in the appropriate BFS container and initiate compatibility and stability studies while making every effort to minimize drug loss.

CONTROLLING DRUG TEMPERATURE THROUGHOUT ASEPTIC BFS FILLING

At ApiJect, our engineers have developed a proprietary temperature management process that enables BFS to fill-finish a wider range of temperature sensitive biologics and vaccines than standard BFS manufacturing setups. Methods we employ to achieve this temperature management through the primary packaging process include designing containers with optimized wall thickness that absorb less heat; maximizing cooling of the drug just before filling; an improved mold-cooling circuit; the use of special handling procedures during post-manufacturing; and reducing the container surface area in contact with the drug product.

These and future BFS advancements are the result of continuous R&D investment by ApiJect so we can best help your team reliably fill-finish their product in customized BFS molds that have been designed with our clients and CMO/CDMOs in mind.

COMPACT SUPPLY CHAIN

BFS, and ApiJect drug delivery systems in general, use an alternative supply chain from traditional glass vial and syringe formats that is easier to manage, and each stage is efficient and flexible.

The raw material used in BFS is pharmaceutical-grade polymer resin (e.g. Low Density Polyethylene – LDPE). Resin can be widely sourced in major markets, helping relieve material procurement concerns that may factor heavily into other drug delivery formats.

In addition, the entire BFS fill-finish process can be done in one or two facilities, with the BFS line requiring approximately 5,000 sq. ft. and the secondary packaging line an additional 14,000 sq. ft.

This compact, alternative supply chain is designed to enable pharma partners who fill-finish their drug product in our delivery systems to reliably meet anticipated demand, even when traditional fill-finish supply chains become overwhelmed by production requests or when traditional fill-finish lines cannot readily source key manufacturing components or materials.

APIJECT IS EXPANDING BFS FOR PREFILLED INJECTABLES

Our experts marry the efficiency and flexibility of BFS with attachable plastic components to create prefilled drug delivery systems. This approach has the potential to enable scalable manufacturing of single-dose prefilled formats (e.g. prefilled syringes) whose cost-efficiency can typically only be found in multi-dose presentations.

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MEET OUR TEAM

To learn more about how ApiJect is expanding BFS to package sterile liquid pharmaceuticals in scalable, prefilled drug delivery devices, contact our experts at solutions@apiject.com.

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FOR MORE INFORMATION:

Blow-Fill-Seal:
visit https://bit.ly/3l27Qwy

Expert Content Library:
visit https://bit.ly/3lZrEZm

Intro to BFS Video Series:
visit https://bit.ly/3yM7aip

Manufacturing:
visit https://bit.ly/3YwKiOc

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