apiject™

Blow-Fill-Seal

KEY BENEFITS OF BFS

- **Sterility Assurance**
  Advanced aseptic processing that forms, fills, seals in a contained ISO 5 area with no human intervention
- **Unit Dose**
  Helps prevent mis-dosing and contamination
- **Enhanced Safety**
  Little to no manual interventions during production
- **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
- **Customization**
  Polymer allows you to shape for brand or product customization capable of serving many markets from saline to liquid vaccines

AN ADVANCED FILL-FINISH PROCESS

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

BFS AS A SOLUTION FOR COMPLEX FORMULATIONS

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

CONTROLLING DRUG TEMPERATURE THROUGHOUT ASEPTIC BFS FILLING

At ApiJect, our unique BFS container and process have been designed to cool the liquid drug product faster than the typical BFS process. We employ several methods to accomplish successful filling such as use of 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 our pharma partners 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. ApiJect uses Low Density Polyethylene – LDPE). Resin can be easily sourced in major markets, helping relieve any sourcing concerns related to glass vials or syringes.

In addition, the entire BFS fill-finish process can be done in a single facility, 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 reliably enable pharma partners who fill-finish their drug product in our delivery systems to 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.

APIJECT IS EXPANDING BFS FOR PREFILLED INJECTABLES

Our experts marry the efficiency and flexibility of BFS with attachable plastic components to create drug delivery systems. This enables single-dose prefilled formats (e.g. prefilled syringes) that have the manufacturing scalability and cost-effectiveness typically only 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:

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