

Case Study: Specialty Pharmaceutical Bottle Production

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Overview

A customer wanted a pharmaceutical bottle made of a flexible, medical grade PVC material. While blow molding is the preferred choice for bottles utilizing low density polyethylene, the flexible PVC material required an injection blow molding process. The team at Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, was able to design and construct a mold and machine to meet the requirements. This case study looks the process utilized to achieve the end result.

The Challenge

The customer provided a 3D CAD model of the bottle. Forefront Medical's engineering team selected an injection blow molding process as the option best meeting the customer's requirements. There were several advantages with driving this choice:

- **Quality and repeatability:** Utilizing this process the bottles can meet exacting standards of consistent weight, volume and tolerance. It also allows for an exact neck dimensions to ensure bottle and cap will have a proper fit and seal.
- **Cosmetic factors:** The bottle will have thick even walls with nearly invisible parting lines. The process also allows for a variety of surface finishes.
- **Cost effectiveness:** While blow molding requires a single cavity, injection blow molding utilizes molds with as many as 12-16 cavities. The process generates no wasted material. Additionally, this process is accurate enough that secondary processes such as trimming are unnecessary. Auxiliary machines are not required for additional operations.

In injection blow molding, the process begins by melting down the flexible PVC and forming it into a parison or preform, which is a tube-like mini bottle which a hole in one end through which compressed air can pass.

While the customer gives the final geometry of the bottle, it was up to the team at Forefront to develop the parison geometry and design the mold. This required extensive moldflow analysis of the proposed injection blow molding process and product characteristics. The customer's target cost in volume production also needed to be considered in determining the ideal mold design and molding process, since cavitation and cycle time would drive production cost.

Forefront's team also specified the flexible PVC material, matching the clarity, hue and durometer of the customer's current product. Forefront's database of approved materials which have passed biocompatibility and other critical tests helped cut time out of the process. Selecting a material which had previously passed the requisite tests, cut weeks out of the development process plus eliminated the potential issues that could arise if a selected material had failed testing.

The Process

The design team started by assessing customer requirements and then created a Design Development Plan (DDP). Based on the customer's 3D CAD model, Forefront's team designed the parison geometry and a single cavity prototype mold. A design review which included functional analysis and risk evaluation was held. After the customer's team approved the design, prototyping and verification began.

The design and prototyping process required substantial moldflow analysis on the blow molding process and product characteristics. The prototype mold was designed with a single cavity. The production mold will be multi-cavity. There are three stations incorporated in this process. The first station has injection-core cavities and a slider. In this step the molten material is fed into a hot runner manifold where it is injected through nozzles into a heated cavity and blow stem. The blow stem forms the neck and internal shape of the parison. This process takes about 8-



9 seconds to form the shape and cool to 190 degrees C. The second station is called the blow station and in this step the parison is clamped into a chilled mold and air is blown into it through the blow stem. A bottle shape is formed that matches the mold cavity. The cycle time on the blow station is 12 seconds. In the final step the bottle is transferred to the ejection station. Once cooled and hardened the part is ejected from the open mold. While the injection blow molding process takes slightly more time than an extrusion blow molding process, it offers a higher degree of accuracy and repeatability.

The team used a gated design process to enable tooling development to begin as early in the design process as possible. The tooling design process included a design for manufacturability (DFM) phase which was followed by development of the mold specification. Following a design review, mold fabrication began at a third party mold fabrication house. This was followed by a testing and debugging phase which included a dry run and analysis of product first off the tool at the mold manufacturer.

The Results

The customer is evaluating the samples. The mold and an injection blow molding machine shipped have been shipped to Forefront. Initially, production will be done using the single cavity mold. As volumes increase a multi-cavity mold will be designed and fabricated.

Once the machine is in place, production processes will undergo a validation phase with performance qualification to user requirements, operational qualification to functional requirements, installation qualification to design specification and installations.

About Forefront Medical

Forefront Medical is a global medical device contract manufacturer with five locations. Singapore is Forefront's headquarters, as well as home to our Design Engineering Center and specialty manufacturing. Jiangsu and Xiamen, China, are additional manufacturing locations and are also China FDA Registered. Shanghai, China, Farmington, CT USA and Riel, Netherlands are regional Business Development offices which assure our technical sales teams are close to our customers for local, responsive assistance.

We have developed extensive capabilities with implantable PEEK micro-molded components, laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding and multi-lumen catheters, infusion sets, wire reinforced tubes, optically clear components, patient monitoring devices and other specialty products.

Each of our locations has state of the art manufacturing capabilities that include class 100K clean rooms for extrusion and injection molding, complimented by class 10K clean rooms for assembly and packaging. Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485, ISO 9001 and FDA Registered. Forefront is a wholly owned subsidiary of VicPlas International Ltd, who is listed on the SGX Main Board, Singapore stock exchange.

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