



Five Reasons to Select a Contractor with In-House Tool Design

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Overview

To some, tooling may appear to be simply one more non-recurring engineering (NRE) cost in a product development process. However, in medical disposables manufacturing, it is also the single most important item in ensuring that quality and cost objectives are met. The quality of the tooling design and fabrication process dictates the amount of secondary processing options needed for the product, the contractor's ability to control key parameters in the process likely to affect product quality, production throughput and the life of the tool. Is there an advantage in selecting a contractor with in-house tool design capability rather than a utilizing a separate tooling manufacturer? This paper looks at five reasons why the answer to that question should be "yes."

Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, considers tool design and fabrication to be a critical part of its vertical integration strategy. The five benefits that this strategy provides customers are:

- Closer alignment between product design and tooling design teams
- Shorter product development cycles
- A more robust approach to manufacturability
- Stronger focus on maintenance costs and tool life
- Broadest range of tooling options.

Closer Alignment Between Product Development/Tooling Development Teams

One of the advantages of an integrated approach to product design and tool design is that teams can closely coordinate their activities and knowledge base. This increases the overall efficiency of the product development process since all team members contribute to the process.

Forefront Medical's team uses a standardized process in which customer requirements are assessed and a Design Development Plan (DDP) is created. A customer specification is then developed and market inputs are collected. Once the customer specification is approved, 3D CAD models are developed and analyzed. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began.

When tooling design and fabrication are integrated into the product development process, tooling options, costs and constraints can be evaluated concurrently with product design decisions. Communication is streamlined, which minimizes time and cost. Forefront Medical enhances this by having standardized software tools in its US Technical Center, Singapore Design Center and China full-scale commercial tool room. Cimatron software is used for tool, hot runner and cooling system designs. Mold-flow software is for mold-flow analysis and to support Design of Experiments (DoEs) to optimize the design and molding parameters when those parameters are not resident in their existing library. Moldex3D software is utilized for molding process simulations to test assumptions prior to tool fabrication. This standardized approach enables tool designers to easily demonstrate the likely performance of the tool under review to the customer's team during the product development process.

**Shorter Product Development Cycles**

Not surprisingly, in-house tooling development can shorten the product development process by several months. This is driven by several factors. First, in Forefront Medical's model, a gated design process enables tooling development to begin as early in the design process as possible. The Company has taken a vertically integrated approach to tooling fabrication and use of its in-house resources often cuts another 2-3 months off of product development time. The tooling design process includes a design for manufacturability (DFM) phase, followed by development of the mold specification. As mentioned earlier, mold-flow analysis tools are used to ensure efficient molding with minimal scrap and minimization of secondary finishing processes. This computer analysis minimizes design iterations on tooling. Tooling iterations are a key performance indicator (KPI) for Forefront Medical's engineering team. The KPI target is no more than 2-3 iterations per product development process.

Forefront Medical also maintains a detailed library of injection parameters related to the best mix of injection pressure, speed and other variables based on materials used. With standard molds and resins, developing optimal injection parameters utilizing this library typically takes two hours.

Tooling fabrication time is also reduced. Forefront Medical's vertically integrated tooling fabrication capabilities typically reduce tool fabrication lead-time by 1-2 months when compared to third-party tooling companies. The Company also maintains in-house resources for the scale up of molds and tools, pilot runs and validations.

Forefront Medical further reduces product development cycle time by providing in-house rapid prototyping in support of the product validation process while hard tooling is in development. This prototyping capability includes Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems for rapid prototyping.

A More Robust Approach to Manufacturability

A primary benefit of using a tooling development team that is part of a contract manufacturer rather than a standalone tooling firm, is that it ensures the design process aligns well with production processes. The earlier manufacturability issues are analyzed in tooling development, the less expensive the tooling design modifications will be. Working with a design team that is analyzing design for manufacturability early in the product development process eliminates added design spins, enhances quality, and optimizes cycle time to produce higher yield, which reduces cost.

Forefront Medical's mold fabrication process includes a testing and debugging phase which incorporates a dry run and analysis of product first off the tool. Design assumptions related to target labor utilization and run rate are evaluated during the validation process. Changes are made if that analysis indicates assumptions were flawed. Production processes undergo a similar development and validation phase. The goal is to lower cost and provide superior quality by minimizing use of secondary processes.

Stronger Focus on Maintenance Costs and Tool Life

Another benefit of using a contractor with in-house tool design and fabrication capabilities, it is that normally there will be more extensive tool room resources available. This ensures a robust preventative maintenance program that extends the life of each tool, helps minimize unscheduled downtime and contributes to high product quality. Plus, an in-house tool room minimizes the downtime and cost



associated with tool maintenance and repair since the tool can stay in the factory instead of being shipped to a third party tool repair facility.

Forefront Medical operates a full scale commercial tool room with integrated support from the Singapore team. This provides the resources necessary to maintain tooling on-site.

Broadest Range of Tooling Options

The best reason for selecting a contractor with in-house tooling design and fabrication capability is that this provides the broadest range of tooling options. Use of in-house resources opens the door to all of the advantages listed above. However, if the tool features or complexity dictate a need to use a third-party tool fabrication house, that option remains available. And, if a third party tooling fabrication house is selected, contractors with in-house tooling capability have the expertise needed to manage that process efficiently and cost effectively.

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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