Outsourcing Best Practices Series

Issue 3

Five Ways Your Supplier Should be Cutting Time in Product Development

April 24, 2014

Introduction

Medical device manufacturers are under continuing pressure to cut cost while delivering superior quality. The amount of identifiable cost that can be taken out of a product through alternative materials and lower cost labor markets is finite, particularly given materials specifications, quality considerations and the fact that disposable medical device assembly typically involves highly automated processes.

A key cost benefit of outsourcing can be the ability to minimize the fixed cost associated with product development and production, since the contract manufacturer shares some of those resources over multiple customers. However, an even larger benefit is the ability to garner the expertise of product development teams who support a broad range of product applications and geographies. In the medical disposables market, contract manufacturers define themselves by their ability to add value and efficiency over the full product lifecycle. The focus on cutting time and cost begins in product development.

For example, the product development team at Forefront Medical , a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, has average product development cycles of 8-9 months. The team attributes its success in regularly shortening product development cycles to its ability to provide superior solutions in five key areas:

- Materials selection
- Design process
- Tooling design and fabrication
- Prototyping
- Validation infrastructure.

Materials Selection

Using materials that have previously been tested and approved within the regulatory environments associated with the product can cut 4-5 months from a product development cycle. It's also important to note that the 4-5 months represents a single testing cycle. If the material has failed testing, a new material must be selected which then restarts the 4-5 month testing cycle.

Forefront Medical maintains a database of approved materials which includes a full range of medical-grade polymers. While the best material will vary depending on application, cost considerations and desired functionality, Forefront Medical's team is often able to recommend pre-approved materials choices to reduce product development time.

Design Process
Standardized product development processes that are aligned with regulatory and validation testing requirements cut time and ultimately reduce cost. A standardized process also makes it easier for the device manufacturer's product development team and the contractor's team to understand what resource gaps need to be addressed at the beginning of 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.

Tooling Design and Fabrication
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 the design for manufacturability early in the product development process eliminates added design spins, enhances quality and minimizes non-value added processing. Additionally, vertically integrated tooling capability can also cut time from the design cycle.

Forefront Medical utilizes a gated design process to enable 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. Mold-flow analysis tools are used to ensure efficient molding with minimal scrap and minimization of secondary finishing processes. 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.

The 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.

Prototyping
In-house rapid prototyping capability also contributes to reduced product development time by cutting lead-time in the product validation process. Forefront Medical's prototyping capability includes Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems for rapid prototyping. The Company also maintains in-house resources for the scale up of molds and tools, pilot runs and validations.

Validation Infrastructure

One of the most challenging aspects of the medical device market is meeting the regulatory requirements of different markets. The high level of automation associated with many disposable medical products makes sourcing regionally less cost competitive. Working with a contract manufacturer capable of supporting a global device marketing strategy in terms of validation testing and quality infrastructure saves time and improves economies of scale.

Forefront Medical has a dedicated Regulatory Affairs team whose responsibilities include product registration and CE marking; maintenance of the Device History Record (DHR) and technical file; biocompatibility testing; validation and support sterilization; updates on regulations and communication of new/revised regulations; and intellectual property protection.

All Forefront Medical facilities are registered to ISO 9001:2008 and ISO: 13485:2003. All facilities are also compliant to MDD 93/42/EC which is the Medical Devices Directive for European Community, MHLW Japan's Pharmaceutical Affairs Law (PAL) and Ministerial Ordinance #169, ISO 15378 which is focused on primary packaging materials for medicinal products, ISO 14001 which is focused on environmental management, ISO 18001, which is focused on occupational health and safety management, and ISO 27001, focused on information security management. All facilities are FDA and Japan registered as foreign contract manufacturers. Its JiangSu, China facility currently holds a FDA Establishment Registration and Class 2 Product Registered (510k), as well as China FDA (CFDA).

Forefront Medical also focuses on supplier quality via a stringent supplier selection process plus a regulatory materials qualification process related to each product. Suppliers are required to undergo a monthly assessment of quality and delivery performance. There is also a rigorous incoming inspection process to ensure that every batch/lot meets acceptable quality levels.

Conclusion

Cutting time from the product development process requires focused expertise and robust systems. That investment typically provides dividends in terms of cost competitiveness and superior quality that continue over the full product lifecycle.

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 laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding 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.

Visit www.forefrontmedical.com to learn more about our capabilities. For a confidential review of your project, please complete our enquiry form at: http://www.forefrontmedical.com/enquiry.html, email us at: appl_dev@forefrontmedical.com, or call +1 (860) 255-7610 (Europe and America's) / +86 21 6062 7177 (Asia).