Outsourcing and The Voice of Customer

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The benefits of outsourcing can vary widely. The determining factor is often the quality of the relationship. Medical device manufacturers know their market, but may not know the best manufacturing strategy to address the challenges they face in commercialization. The best partnerships create a collaborative relationship that blends device manufacturer and contract manufacturer expertise. In identifying potential contract manufacturers, strong focus should be placed on the contract manufacturer's processes for assuring the voice of the customer is active throughout the commercialization process. In this whitepaper, Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, discusses its processes in integrating the voice of the customer into each project.

A Collaborative Design Process

The product development process establishes the framework for collaboration. In a perfect world, both parties understand each other's strengths and weaknesses and seamlessly align. The reality is that without a focused process that prioritizes a collaborative approach to listening to each customer, misperceptions and gaps in communication of requirements or capabilities can negatively impact the working relationship.

Forefront Medical's team eliminates this potential disconnect, through the use of 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. This two-pronged approach of pulling information from the customer combined with studying the market helps ensure the initial specification adequately identifies all critical requirements. The customer specification provides a written document that aligns the teams in a shared vision.

Once the customer specification is approved, 3D CAD models are developed and analyzed to test assumptions related to the design and manufacturing process. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began. This phased process enables an evolutionary path to be taken should analysis or a review step indicate a change in approach would be beneficial.

Forefront's approach is designed to add its team's manufacturing expertise to fill gaps in its customers' product development process. For example, Forefront 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, the product development team is often able to recommend pre-approved materials choices to reduce product development time. 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. This can help expand available materials

options in projects where new materials are needed to achieve functionality, fit or competitive advantage goals.

Forefront's in-house rapid prototyping capabilities support the product validation process while hard tooling is in development. This prototyping capability includes SLS and MJM systems for rapid prototyping, enabling a more comprehensive early stage review of product components than achievable in computer simulation alone.

Forefront also addresses the challenge of distance among product development teams typically present in offshore product development and manufacturing efforts. Its U.S. Technical Center utilizes the same software tools present in its Singapore Design Center and China full-scale commercial tool room. This enables teams to communicate in a time zone convenient to customer design teams and supports U.S-based face-to-face meetings.

Joint Focus on Addressing Competitive Pressures

Developing a manufacturable product is only part of the equation. The road to successful product commercialization often requires an evolving approach that focuses on reducing product cost over time. Manufacturing expertise, the ability to look at variations in manufacturing automation strategy as volumes increase and a focus on total cost are critical elements of successful commercialization processes. The voice of the customer is important in identifying the market challenges that must be addressed. The ultimate complement to this process is a contract manufacturer capable of taking that information and offering creative solutions to address those challenges.

For example, when a customer who had developed a patentable concept involving measurement of patient oxygen exhalation came to Forefront, the team was able to fine tune the concept in ways that hit both initial pricing targets and provides a path to lower cost as volumes increase over time.

The original concept required development a mask with ports, luers and a luer lock. The design as originally conceived would have involved a mask development effort along with associated tooling prior to doing any proof-of-concept testing. Forefront's design team recognized that this initial cost could be minimized by modifying an over-the-counter (OTC) mask design to include ports that accommodated the luers and the luer lock. Utilizing an OTC component enabled the customer to test the concept with virtually no upfront cost.

The OTC mask design enabled the customer to prove out the concept and sell the product concept to distribution partners with minimal upfront capital investment. Forefront's team then designed a custom mask that is molded with the ports. The luers and luer lock are added in a secondary assembly process.

Forefront's engineering team has also developed some lower cost materials options that can be phased in later in the product's lifecycle as volumes increase.

The logistics equation and supply chain requirements are also evaluated in Forefront's commercialization process, and where appropriate lower cost or more efficient options are suggested by Forefront's team. Collaboration in this area helps reduce total product cost, often in ways the customer did not initially consider.

Ability to Listen to the Voice of Customer's Customers

To better address the challenge of ensuring cost reduction over the life of the product, Forefront Medical developed a continuous improvement value-added process to identify opportunities for cost reduction and/or improvement in the overall competitiveness of the products it produces by evaluating internal processes and surveying end users. Internally the focus is on identifying production bottlenecks and long lead-time issues, and includes feedback from operators and technicians. Externally, the focus is on ease-of-use. The team develops a list of potential improvements and then selects the top priorities. A timeline is developed and progress is tracked. The project is closed once 80-90% of the improvements have been achieved. This process varies from a traditional Value Analysis Value Engineering (VAVE) process in that VAVE projects tend to be completely cost driven. In this process, the goal is to eliminate non-value added cost and increase the customer's market share.

For example, in a project that involved a drug infusion dosing pump, Forefront's team discovered from post-development interviews with end users, that the 1.5 meter-long line was tangling. The design was modified to include a spring section that eliminated the tangling issue.

Conclusion

Successful outsourced medical product commercialization leverages both expertise from both customer and the contract manufacturer. Establishing a process that aligns the voice of the customer and the expertise of the contract manufacturer's product development team is critical to establishing that level of collaboration.

About Forefront Medical Technology

Forefront Medical Technology 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 and Farmington, CT USA 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.

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