Case Study: Specialty Drug Delivery Systems

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Overview: Development of specialty drug delivery systems requires both strong materials and mechanical engineering expertise. This white paper looks at the process Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, used in designing a Class III drug delivery system used in a chemotherapy application.

In this case the customer was a Tier One contract manufacturer, who built specialty kits for an original equipment manufacturer (OEM) of specialty drug delivery systems. The contract manufacturer was looking for a medical disposable manufacturer in Asia who met FDA regulatory requirements and could supply required components for their production operations using OEM-specified materials. The contractor also wanted the supplier to provide long-term cost reductions in line with the OEM's requirements.

The Challenge

The customer provided the basic design for the mechanism and the components. The key design challenge involved identifying materials that met the customer's requirement of Di 2-ethylhexyl phthalate (DEHP)-free and had the required bonding strength among components and tubes. This was complicated by the fact that one component supplier had been previously selected by the OEM and any design modifications would need to incorporate that component and supplier.

The Process

The design team started by assessing customer requirements and then created a Design Development Plan (DDP). A customer specification was developed and market inputs were collected. Several studies were done on solvents able to provide the required bonding strength.

Forefront's database of approved materials which have passed biocompatibility and other critical tests helped cut time out of the process. Selecting a solvent, additive and materials 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. Second, the overall design process and design tools were standardized so internal teams collaborating globally had the same frame of reference.

Once the customer specification was approved, 3D CAD models were developed and analyzed. 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 team used a gated design process to enable tooling development to begin as early in the design process as possible. A combination of in-house rapid prototyping capability and in-house tooling design and fabrication capability helped shorten the product development cycle. The tooling design process included a DFM phase which was followed by development of the mold specification. Following a design review, mold fabrication began. This was followed by a testing and debugging phase which included a dry run and analysis of product first off the tool.

Production processes underwent a similar development and validation phase with performance qualification to user requirements, operational qualification to functional requirements, installation qualification to design specification and installations.

The Results

Forefront's team was able to design a product that met the customer's specifications for form, fit, function and cost. An FDA audit at the beginning of the process was conducted with no issues found, underscoring the benefit of working with a team knowledgeable in stringent quality requirements. Forefront's combination of materials

and engineering expertise has ensured that a design and manufacturing process has been developed that is capable of achieving the customer's cost targets.

Longer term, Forefront has several ways in which can support continuing reduction. First, Forefront has a continuous improvement value-added process that supports its efforts to identify opportunities for cost reduction and/or improvement in the overall total product cost 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 market share.

Second, Forefront periodically evaluates the less visible costs associated with supplying products globally. Changes in logistics costs, raw material supply chain trends and trade agreements are monitored for cost reduction opportunities.

Few contract manufacturers can be all things to all their customers. Selecting a specialized manufacturer of disposables such as Forefront Medical, enabled this Tier One contract manufacturer to seamlessly support its customer without increasing its fixed costs.

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.

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 5175 1516 (Asia).