Is Your Contract Manufacturer's Product Design Team Constrained by Production Capability Limits?

May 3, 2018

One of the key benefits of using a contract manufacturer for both design and manufacturing is the ability to work with a product design team that is experienced with manufacturing. This can eliminate design errors that could otherwise increase tooling costs and secondary processing costs. However, this option can also result in a design team that limits design choices to in-house production processes. The optimum solution is choosing a contract manufacturer with a broad enough range of capabilities that all design options that would make sense for the product are considered. Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems offers a vertically-integrated, one stop solution. Forefront's capabilities include mold design, Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems for rapid prototyping, injection and blow molding, extrusion, metal fabrication, and clean room assembly capabilities.

The following two examples look at ways Forefront's team has focused on solutions that incorporated multiple types of manufacturing processes or overcame production-related constraints that have traditionally limited design options.

Broader Options for Designing Competitive Advantage

Competition continues to increase in the single-use medical device market. Product cost, feel, functional capabilities, ease-of-use, biocompatibility, patient comfort, industrial design, compatibility with other devices and quality are sources of competitive advantage. Often these aspects of competitive advantage require work with specialized materials.

In this case the project involved designing and molding a plastic valve set which was functionally equivalent to the metal valve set currently used in a diagnostic product. The challenges included:

- Identifying materials with correct level of rigidity and strength to be functionally equivalent to the metal valve set
- Ensuring that the plastic components performed identically and felt similar to their metal counterparts to a doctor performing a specialty procedure
- Designing a complex mold that could produce parts with conformance to extremely fine tolerances.

The valve assembly to be replaced had five separate components: a stem, end cap, snap cap, gasket and spring. Multiple materials were required. The design team began the project with a brainstorming process to determine the likely best materials options. Thermoplastic elastomer (TPE), polypropylene, polycarbonate and acrylonitrile butadiene styrene (ABS) were tested as replacements for the stainless steel parts. ABS offered the lowest cost and the best level of rigidity. This was important because the ABS part was sliding against a metal component during procedures and the plastic part needed to be able to withstand the friction of the sliding motion. Another benefit was the compatibility of ABS with

TPE. Components which would come in contact with the doctor's glove needed to be soft with no sharp edges that could tear the glove. TPE met that criteria and it also provided the best bonding properties with the ABS components.

To better understand the functional requirements, the design team closely studied a working unit in their lab. The plastic valve set not only needed to perform functions identical to those performed by the metal part set, it also needed to feel the same to the doctors using the product.

One area of concern was friction. As mentioned earlier, there is an ABS part sliding against a metal part and that operation needed to be as frictionless as possible. The team was able to work with an ABS supplier to specify a material with an anti-friction property that met the requirement.

Design of Experiments (DoE)s were used to fine tune the design of the spring used for a cushioning effect, in order to develop a spring that provided the same "feel" to doctors as the metal spring.

The most significant challenge involved mold design. The design of plastic components is fundamentally different from that of metal components because the manufacturing process is different. Fabricated metal parts are formed through machining, which supports very tight tolerances, precisely formed grooves and sharp corners with 90 degree edges to achieve a tight seal. Conversely, plastic parts are formed via an injection molding process which traditionally has wider tolerances and delivers a less precise cylindrical form.

The tolerance for the components used in one of the valve assemblies was 5 microns, which gave a window of +/-2 microns. When a part is injection molded, there is a possibility of non-centering. Additionally, cylindrical molded parts are typically not a perfectly shaped cylinder. The initial parts did not have the required tolerance and as a result, there was leakage in the suction valve.

The team decided to change the mold and the molding concept. The two-cavity mold was redesigned to include a slide-core mechanism for forming the cylindrical portion of the part. The critical dimensions of the part were machined inside of the slide-core mechanism during the injection molding process. The team was to develop a final machining solution that delivered a part with +/-3 micron tolerance.

As this example illustrates, analysis of the best options required not only a broad knowledge of molding and materials options, it also required the ability to design a mold that could support far narrower tolerances than commonly found in injection molding. The ability to assign a co-located multi-disciplinary team to analyze the design goals, perform DoEs and recommend a solution was possible due to Forefront's vertical integration. Additionally, with a vertically integrated contract manufacturer, there is often more willingness to invest in expanding hybrid capabilities that bridge multiple in-house technologies for projects that will provide a return on that investment.

A More Creative Approach to Product Redesign

In another case, a manufacturer of products used for foreign particle management in the esophagus found that the market for its product line was no longer growing. The Company decided that a redesign of the product line was the best way to increase market share.

Forefront's team recommended converting the manufacturing process used for the tubing from a dipping process to the combined use of extrusion molding and injection molding. The team also

recommended changes in the materials composition for other components used in the product. This paper discusses lessons learned in the redesign and qualification process and the overall results.

The previously-used dipping process involved dipping the product multiple times to form layers. There were three primary disadvantages of the dipping process. First, it produced a sticky tube, which created a high frictional force during insertion of the endoscope and impaired its key function of serving as a guide for insertion of the endoscope. Second, the sticky tube also was difficult to insert in patients. Finally, it was costly since manufacturing the tubing involved several rounds of dipping.

The dipping process limits the device to a single material type of same shore hardness on the entire device, whereas Forefront's developed process of vertical extrusion molding and injection molding allow the use of different types of material and concomitant shore hardness at different parts of the device, based on the functional requirement.

The product line included 25-centimeter and 50-centimeter versions of one product plus a third product that was 82 centimeters long. Components included inner tubing, outer tubing with a tapered tip, a distal cuff, and a spring.

Under the redesign for the 25- and 50-centimeter product versions, the wire-reinforced outer tube and the inner tube were extrusion molded and the distal tip and cuff were injection molded. The 82-centimeter product was too long to construct as a single piece, so it was designed in three sections with couplings optimized to provide the right degrees of flexibility and rigidity within different sections of the tubing to enable a physician to easily insert and guide the longer product down the esophagus.

The taper on the tip enables the tube to be inserted without mucosal tearing and/or shearing. To cater this requirement, this distal tip was injection overmolded with a softer PVC resin on the reinforced body. The cuff needed to tightly seal to minimize the risk of body fluid contamination. Finding the right material combination to achieve those functional requirements required several rounds of testing material combination selections.

On the 82-centimeter product, four-to-five different types of materials were selected for the overmolded harnesses that would join the sections. The sections needed a coupling that had the right degree of flexibility for moving through the patient. The product was originally made of PVC. Initially, a polyresin was considered for the couplings. A stainless steel coiling joint with overmolded silicone is now the preferred option.

Extrusion with spring reinforcing was selected as preferred process for the outer tube because a normal extruded tube wouldn't work well with the spring. That said, in initial molding tests, the spring wasn't getting into the right pitch. The team had two options: lock the spring into position or have it loose in the inner tube. They chose to create a groove in the tube for the spring, insert the spring and then overmold.

The longer tube was too long for the molding/solvent dipping process used on the shorter tubes. For this product, the coil is embedded in the mold, since there is no pitch variation. Forefront's electro discharge machining capability enables fabrication of molds with tolerances of 3 microns. One challenge was the gauging inside the mold. The tube needed to have a smoother finish since it would have tissue contact. This meant that only a single point gauge could be used in mold for in-process measurement.

Moldflow analysis software was used to optimize the molding parameters to the point where a single point gauge was acceptable.

Forefront's vertical extrusion machine capability was also beneficial. Vertical extrusion improves quality in thin-walled tubing by having easier alignment between the press ram and tools and uniform deformation due to uniform cooling of the billet in the container.

As a result, both cost and lead-time were reduced. The cost reduction was in the 30-40 percent range, since the production cycle time of the previous process was much longer. Quality improved because the manufacturing processes became highly automated and the processes were tightly controlled. Functionally and user-friendliness was also improved since friction was no longer a factor with smoother, non-sticky surfaces. Customers also found that the three sections in the longer product provided an instrument that feels soft and flexible on the front, yet more rigid on the back as the tube is inserted further into patient.

Conclusion

Choosing a contract manufacturer with a broad range of production capabilities and an experienced product design team opens the door to a broader range of design and redesign solutions. Collaboration between the design and manufacturing teams eliminates the issues that teams operating in silos commonly experience, while reduced product development time and enhancing production efficiency.

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.

Visit www.forefrontmedical.com to learn more about our capabilities. For a confidential review of your project, please complete our enquiry form at: http://forefrontmedical.com/contact-us/, email us at: appl_dev@forefrontmedicaltechnology.com, or call +1 (860) 255-7610 (Europe and America's) / +86 021-5175 1516 or +86 021-5175 1513 (Asia).