Outsourcing Best Practices Series

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The Value Equation: Four Benefits Your Contract Manufacturer Can Provide

The Value Equation: Four Benefits Your Contract Manufacturer Can Provide Beyond Assembly

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Outsourcing manufacturing is a good way to reduce production costs by accessing shared manufacturing resources. That said, when the benefits a contract manufacturer can bring to the product commercialization process are fully analyzed, there is often significant value beyond access to shared manufacturing resources. This value equation can also include:

- Reduction in product development cycle time
- Improved design for manufacturability
- A continuous improvement focus over the life of the product
- Supply chain and logistics expertise.

The combination of these elements can help improve competitive advantage, control costs and ensure that quality goals are consistently achieved. Supplier selection should evaluate not only assembly capability, but also the ability of each contract manufacturer to provide a solution that encompasses these additional points of value.

In this whitepaper, Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, provides examples of ways these points of value have benefited its customers.

Reduction in Product Development Cycle Time

For contract manufacturers with internal product development engineering capability, product development is a disciplined and repeatable process. The benefit of collaborating with this type of team can be elimination of many of the learning curve issues that can slow the commercialization process.

In new product development, Forefront Medical's team uses a standardized process in which customer requirements are assessed and a Design Development Plan (DDP) is created. The DDP is followed by a customer specification and collection of market inputs. This approach enables Forefront's team to rapidly assess customer requirements, present design and manufacturing options and move forward with a design that incorporates all customer requirements and utilizes the optimum manufacturing technology or technologies for those requirements. Variables such as the feel of a device in a surgeon's hand, the ease of keeping tubing arranged by a hospital bed and patient comfort are all considered as these choices are made.

On the custom parts side of the equation, once the customer specification is approved, 3D CAD models are developed and analyzed, helping to optimize tooling performance prior to fabrication. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began.

To help shorten product development cycles, Forefront Medical also 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.

On the electromechanical side of the equation, Forefront's design team provides electronics design and PCB layout, as well as software development services. Mechanical and packaging design can also be supported. Prototyping and validation are also provided.

As part of the new product introduction (NPI) effort, Forefront collaborates with its customers on identifying any needed suppliers; risk management; machine, tools and process validation; product bio-compatibility and stability validation; sterilization validation including sealing integrity; and packaging ship testing.

Forefront also operates a U.S. Technical Center to make it easier for U.S. customers to communicate with personnel in a time zone convenient to their normal work schedule. Forefront's management team, program management team and engineering team are fluent in English and multiple Chinese dialects, ensuring that project discussions are fully understood at all levels of the manufacturing process.

This broad range of engineering disciplines and manufacturing capabilities combined with software modeling capability creates a multi-disciplinary team focused on reducing time to market by working smarter.

Improved Design for Manufacturability

One of the benefits of team collaboration during the product development phase is the ability to optimize the design to improve efficiency in the manufacturing process.

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. During product development, design for manufacturability (DFM) recommendations are made to ensure minimal secondary processing. Tooling and assembly lines are optimized for efficiency. Prior to tooling fabrication, simulation software is used to ensure the tooling design will achieve the desired cost and quality targets.

Industry-standard software is used for tool, hot runner and cooling system designs. Mold-flow software is used 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 Forefront's existing library. Moldex3D software is utilized for molding process simulations to test assumptions prior to tool fabrication. Forefront maintains a detailed library of injection parameters related to the best mix of injection pressure, temperature, speed and other variables based on materials used. With standard molds and resins, developing optimal injection parameters utilizing this library typically takes two hours when injection molding is part of the production strategy.

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.

Mold complexity also influences machine size, but a creative design team may be able to work around that constraint. For example, on one high volume part, Forefront's team determined that a 64-cavity mold was needed to support the anticipated second year volumes. As originally designed, the mold was too large for a 220-ton injection molding machine. Utilizing a higher tonnage machine would increase cost since the machine consumes more space and energy, so the team needed to change the mold assembly layout to reduce the size of the mold. A key challenge was that this part was small and formed by the core, cavity and sliders.

The team needed to develop a design that had sufficient space between cavitation, runners and a comfortable ejection system. They designed a mold without thin steel, positioned the layout accordingly, so that a single hot runner tip would inject the plastic to two parts and designed a hot runner system that met those requirements. This reduced the space required enough to utilize the lower tonnage 220-ton machine.

A Continuous Improvement Focus Over the Life of the Project

It is common for OEMs with electronic products to change contract manufacturers multiple times over the life of a product because assembly line equipment is interchangeable. Conversely, products with customized tooling and assembly/packaging automation often stay with a single contract manufacturer. That said, changes in demand, market advantage or external costs often drive a need for improvement in the cost equation to balance the cost impact these variations drive. Selecting a contract manufacturer with a disciplined approach to improving production efficiency can help in that effort.

Six Sigma Green Belt training is in place in all Forefront facilities, creating teams with enhanced problem solving skills to lead continuous improvement focus in each facility. The core tools used to drive this process include:

- 7S workplace organization
- Poka Yoke mistake proofing technique
- 8D systematic approach problem solving methodology
- Risk management & Process Failure Modes and Effects Analysis (PFMEA)
- Statistical process control.

The teams start by developing a project charter which defines the problem statement, clear business objectives and benefits drivers. A Gemba workshop is then conducted with participation from various functions to identify potential areas of improvement, together with a time study to pinpoint bottlenecks. In Lean philosophy, Gemba means the place where value is created, and the technique is derived from the Toyota Production System. A more commonly recognized corollary in the management world would be Tom Peters' concept of "management by walking around." The Green Belt teams learn from observing the process and talking with production operators about their perspectives. Following Gemba, a focused DMAIC (Define, Measure, Analyze, Improve, Control) methodology is used to initiate the improvement process.

A DMAIC spreadsheet is used to capture information in a concise form. The benefit of this approach is that each identified improvement opportunity is thoroughly analyzed and tested to ensure root causes are correctly identified and the magnitude of the improvement benefit of implementing the corrective action is thoroughly understood.

For example, the team utilized a DMAIC process to identify potential improvements in throughput and cost on a project. Demand spikes had driven a need to switch to air shipment. The team's goal was to implement improvements that lowered overall project cost and also improved throughput to the point where surges in demand could be accommodated within the regular sea shipment schedule.

The team plotted a scattergram over two axes focused on opportunity impact and the effort associated with corrective action. That activity identified four opportunities with some impact and marginal effort. There were another three opportunities that offered greater impact at slightly higher effort and three opportunities that offered similar impact at a much higher effort.

The team then created a current state process map that mapped the production process flow, personnel, cycle time and takt time. They modeled a re-layout of the line for continuous flow vs a work cell arrangement. They then focused their efforts on two steps in the process: packaging the product in a tray and final sealing operation. The workstations were rearranged to enable operators to work with components more efficiently in a smaller space by utilizing stackable, color-coded bins to store raw material. Small changes were made to housekeeping and cleaning tools to eliminate dust particles not already eliminated by cleanroom filtration and production attire, reducing the time operators needed to spend cleaning each product during the packaging stage. From a throughput standpoint, the best opportunity for improvement was redesigning the automated sealing machine's sealing plate to have six cavities on each side instead of four. They also worked with the equipment manufacturer to develop a process that utilized both sides of sealing plate, instead of just a single side. The specification for the outer tray was also reviewed with the customer to better identify which visual defects should signal a rejected product. Discussions were also held with the tray supplier to minimize the opportunity for handling or shipping related cosmetic defects.

The result was a 50 percent improvement in throughput and a reduction in the need for air shipments.

Lean Six Sigma provides well-trained teams with a focused process and core tools for evaluating and prioritizing improvement opportunities. Even the best planned projects can have room for improvement when production requirements increase significantly. In the current environment of increasing cost and imbalance between supply and demand, Lean Six Sigma provides Forefront Medical's team with the resources to help mitigate increasing costs while increasing throughput and process yield.

Supply Chain and Logistics Expertise

Logistics management expertise has never been more critical. A contract manufacturer's expertise in regional supply chain identification plus an ability to determine the best shipment strategy for support of the end market can provide substantial savings.

Forefront Medical's team has significant experience in supply chain realignment to reduce logistics costs. Its facility locations have been selected for their proximity to major shipping hubs and support infrastructure such as contract sterilizers. This increases the options it can consider when logistics constraints are impacting delivery times.

Partnering with a contract manufacturer to optimize the product commercialization process ensures that inefficiency and non value-added costs are eliminated. Decisions made in the product development phase are particularly beneficial in this regard. Working with a contract manufacturer's team to continue

this focus on eliminating unnecessary cost in production and logistics further improves competitive advantage.

About Forefront Medical Technology

Forefront Medical Technology is a global medical device contract manufacturer with six 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. Arrow Medical, Kington, Herefordshire, UK, is now a part of the Forefront global capability, specializing in wound care products. Regional Business Development offices are located in Farmington, CT USA and Shanghai, China, and 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, electromechanical 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.

Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485:2016 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 http://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) 830-4637 (Europe and America's) / +86 21 6062 7177 (Asia).