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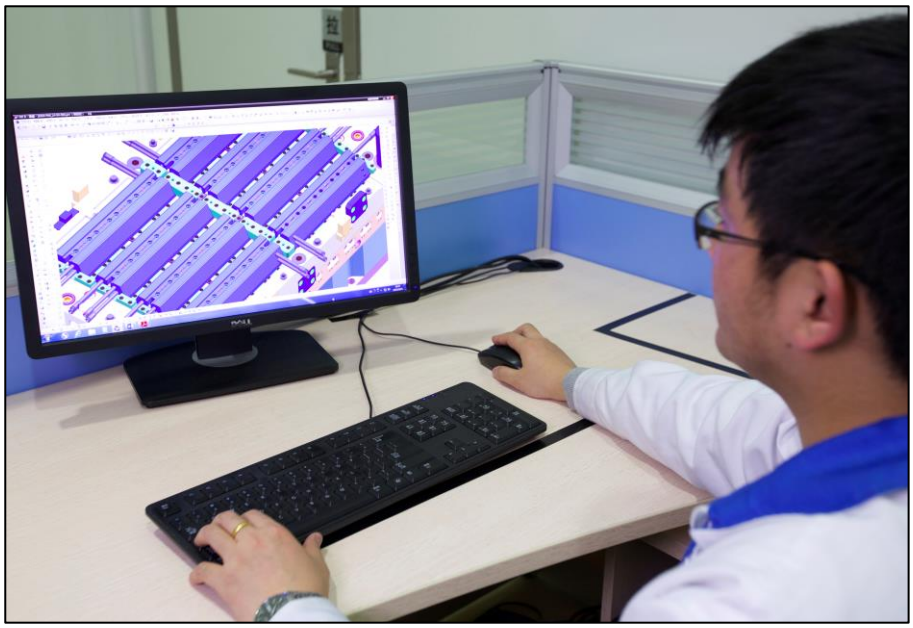

# Are You Teaming with Your Contract Manufacturer to Develop More Competitive Products?

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Contract manufacturers are often viewed simply as factory locations for building product in lower cost regions. While some contract manufacturers fit that "no frills" definition, there are also companies whose design and manufacturing expertise can be leveraged in ways that may enhance product functionality or ease of use, improve quality through greater levels of automation, or reduce cost by eliminating inefficiency. When vertical integration is added to that equation, the options for product improvement benefits increase because the contract manufacturer has a wider range of manufacturing technology options to recommend.

Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, offers this type of end-to-end solution. This whitepaper looks at three ways design and manufacturing expertise is used to improve production outcomes:

- Design for manufacturability
- Continuous improvement in production
- Evaluation over time.

**Design for Manufacturability**

Designing an innovative product is only half the product development equation. The end design needs to be manufacturable to meet both quality and cost targets. This is an area where contract manufacturer expertise can be invaluable, because engineers with manufacturing experience are able to analyze best production technologies, as well as tooling and automation considerations. When this discussion occurs early in the design process, the costs of incorporating these recommendations is much lower.

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, followed by a customer specification and collection of market inputs.

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.

Forefront also 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.

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.

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.

Forefront's team also analyses manufacturing and assembly automation options during this DDP phase, since the ability of the product to meet its volume price target is heavily dependent on the manufacturing and automation strategy meeting cycle times and minimizing labor when production volumes are achieved. While manufacturing processes such as molding, extrusion or metal fabrication and any concomitant tooling are defined by the product design, the automation process can evolve over time as volumes increase.

Forefront's team utilizes a standard DDP for automation. The team evaluates the product, its projected volumes, the fixed costs associated with an automated line and the anticipated length of the project to determine if the benefits provided by automation will outweigh the costs.

When product volumes are difficult to forecast, the team will often start the program with more manual assembly volumes, often for the first year. Once volumes become consistent, the team begins the automated production line design process.

Much of the "labor" eventually done by robots can be done by actual production operators until volumes reach a point where the cost of robotics is less than actual labor cost. Once the basic line concept is designed and computer simulated, determining the breakeven point is fairly easy.

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 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 comprehensive set of support capabilities helps ensure that customers are able to leverage the expertise of Forefront's team and that the team fully understands all customer requirements from the earliest stages of the project. As a result, both sides are able to collaborate on eliminating manufacturability issues and unnecessary cost.

**Continuous Improvement in Production**

While no contract manufacturer can completely eliminate the issues caused by supply/demand imbalance in global markets, it is possible to mitigate that impact by improving internal efficiencies in the manufacturing process.

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. Recent 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.

**Evaluation Over Time**

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.

Teaming with your contract manufacturer in the design phase is the best way to ensure a manufacturable design, utilizing the best manufacturing technologies and levels of automation. When that contract manufacturer also has the capability to work with your team to improve manufacturing efficiency or suggest product improvements over time, market advantage increases.

**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, 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) 255-7610 (Europe and America's) / +86 21 6062 7177 (Asia).*