# Addressing Market Challenges: Are You Leveraging Your Contract Manufacturer's Expertise?

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The imbalance between supply and demand continues to challenge medical device manufacturers. Rising costs, materials constraints and logistics delays have become "givens" in today's manufacturing environment. In the outsourcing realm, contract manufacturers are being tested as never before. However, there is one major difference. Most OEMs' business models revolve around product innovation and an ability to dominate their market niches. Conversely, the contract manufacturing business model revolves around manufacturing expertise and ability to rapidly transform customer orders to delivered products. As a result, there is greater incentive in the contract manufacturing model to find ways to mitigate current challenges. Contract manufacturers who are vertically integrated and expert at addressing logistics challenges may fare better than companies dependent on a broader supply chain to produce and deliver a finished product. Contract manufacturers with a focus on continuous improvement may be better positioned to offset higher costs or increases in shipping lead-time with improvements that shorten manufacturing cycle time.

Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, feels there are four areas where a contract manufacturer's capabilities may be able to improve outcomes in the current market:

- Product launch
- Vertical integration
- Continuous improvement
- Logistics management.

This whitepaper looks at each of these areas and discusses ways Forefront's team applies their expertise.

**Product Launch**

In an era of material and logistics challenges, having a disciplined process for product launch is critical. Both Forefront's product development and product launch processes are designed to fulfill this need.

Forefront's team works with customers who have new products in development or mature products requiring a shift to a lower cost labor market. When either product design assistance or redesign for cost reduction is involved, Forefront's design engineering group works under a Design Development Plan (DDP) process designed to assess customer requirements and define a detailed product specification. The customer specification reflects both customer and market inputs. 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. Tooling performance and throughput assumptions are tested via software modeling. Design reviews which include functional analysis and risk evaluation are completed. After the customer's team approves the design, prototyping and verification begin. This phased process enables an evolutionary path to be taken should analysis or a review step indicate a change in approach would be beneficial. Use of rapid prototyping technologies ensures that the customer team is able to see and handle a prototype as an additional check and balance in the process.

Forefront's Safe Launch™ process helps ensure a robust production validation process, verifying product and process stability in an organized manner through audits during the validation process.

Areas audited include:

- Material receiving and incoming inspection
- Material storage conditions and security
- Work order issuing
- Material issuing and accountability
- Set-up, line clearance and first article inspection
- Production record of good vs. scrap
- Production run with 100% inspection on critical points
- Work order closure to determine if actual quantity aligns with system quantity.

The output of this audit process is a gap analysis on commercial run readiness which leads to development of an action plan. Data collection is used to determine if critical defects are detected. Once all the gaps are closed and pre-defined critical customer and product requirements are met, the team exits Safe Launch™ and begins normal production.

In developing each Safe Launch™ Plan, Forefront's team and the customer's team collaborate to assess potential defect opportunities and define a list of requirements that help prevent defects from occurring. Forefront's team then develops a control plan with checks and balances to prevent defects from occurring where possible, plus inspects CTQ elements to ensure only defect-free product leaves the factory.

Visual inspection of incoming material helps ensure material conformance. Environmental issues that could impact product quality such as storage temperature and relative humidity are also monitored. Products are visually inspected to ensure conformance to product specification following assembly and that required finished goods packed quantities meet customer requirements. When indicated in the control plan, samples are pulled from each production lot for packaging and sealing strength tests. Potential sources of contamination are identified, and measures are taken to ensure that work-in-process (WIP) and finished product will be handled, packed and stored in ways that prevent this contamination issue from occurring.

This highly disciplined process helps eliminate the learning curve issues and miscommunication that can otherwise slow down the product launch process. It also makes it easier to discuss alternative options should current market constraints create unforeseen issues.

**Vertical Integration**

In time-sensitive projects, vertical integration streamlines lines of communication and priorities. Even a normal market, a group of suppliers often has varying priorities, capacity constraints and different recommendations on design modifications. All of these issues can impact the targeted timeline for product development or start of production. Conversely, a vertically integrated contract manufacturer has one set of priorities and a multi-disciplinary team. If demand needs to increase rapidly, a vertically-integrated contract manufacturer can re-prioritize internal resources more rapidly than a company dependent on multiple suppliers for the same processes. Finally, a contract manufacturer with a broad range of capabilities is more able to suggest manufacturing solutions that are ideal for the project, rather than limiting options to a single internal production technology.

Forefront Medical's capabilities include Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems, injection and blow molding, extrusion, metal fabrication, electromechanical assembly, and clean room assembly capabilities.

Use of multiple manufacturing technologies helped reduce time to market on a product development process for a COVID-19 related swab, where Forefront's team was working to specifications provided by the National University of Singapore (NUS).

Forefront's team was able produce initial product using additive manufacturing for speed, while concurrently developing tooling for an injection molded version, introduced later in 2020. The project started in May 2020 and by July 2020, the Company had shipped 1 million 3D printed swabs, which passed all acceptance tests. This ability to apply manufacturing technology to achieve a fast ramp that can evolve into a longer term high volume solution decreases time to market while providing a cost effective solution as volumes increase.

**Continuous Improvement**

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.

**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.

The ability to mitigate market chaos by working smarter has never been more important. Forefront Medical's combination of disciplined processes, experienced team, breadth of manufacturing technologies and supply chain relationships help ensure flexibility in addressing current market challenges.

**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.*

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