# Speed and Scalability: The Advantages of Outsourcing to a Vertically Integrated Contract Manufacturer

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If there is one thing that is predictable in today's medical device market, it is lack of predictability. The COVID-19 pandemic has changed demand for established products, created demand for new products and driven the need for re-evaluating optimum sourcing strategies. One thing that hasn't changed are the benefits of working with a vertically integrated contract manufacturer, rather than multiple, specialized suppliers. A vertically integrated supplier offers a number of benefits including a broader range of manufacturing technology options, more control over the resources of production and a reduction in component markups. However, the two biggest advantages are speed and scalability.

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, looks more closely at the benefits of vertical integration in reducing time to market and initial automation and/or tooling costs.

**Reducing Time to Market**

Not surprisingly, contract manufacturers with one core manufacturing competency and a group of associated suppliers tend to recommend manufacturing technology most closely aligned with their internal manufacturing competency. Comparatively, a vertically integrated contract manufacturer is able to evaluate multiple manufacturing technology options, making design recommendations based on the optimum technology for the product's form, fit, function and cost requirements.

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.

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.

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.

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.

**Scalability**

A challenge with many new products is developing a cost effective manufacturing strategy when product volumes are likely to be low initially. Forefront Medical has a track record of supporting scalability needs, and routinely helping its customers commercialize new products by providing a scalable solution designed to significantly increase capacity and reduce labor cost as volumes grow.

Forefront's team analyses manufacturing and assembly automation options during the 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 processes, 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 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.

Similarly, Forefront's management team also analyzes the build site region and logistics equation, making recommendations, based on optimum build site and supply chain based product end markets.

**Translating These Benefits to Actual Projects**

The following examples help illustrate how Forefront's multidisciplinary engineering expertise and manufacturing capabilities can solve common commercialization challenges.

*Reducing Initial Tooling Costs*

One of Forefront's customers developed a patentable concept involving measurement of patient oxygen exhalation. The design as originally conceived would have involved a mask development effort along with associated tooling prior to doing any proof-of-concept testing. Forefront's design team recognized that this initial cost could be minimized by modifying an over-the-counter (OTC) mask design to include ports that accommodated luers and a luer lock. Utilizing an OTC component enabled the customer to test the concept with virtually no upfront cost.

The OTC mask design enabled the customer to prove out the concept and sell the product concept to distribution partners with minimal upfront capital investment. Forefront's team then designed a custom mask that is molded with the ports. The luers and luer lock are added in a secondary assembly process.

*Reducing Time to Market*

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 over time.

Utilizing the expertise of a vertically-integrated contract manufacturer can increase design options and opportunities for reducing cost, while shortening the product development cycle. This combination of innovation and efficiency can improve competitive advantage and provide a faster response to emerging market opportunities.

**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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