



Contract Manufacturing Basics: Benefits, Challenges and Best Practices

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Contract manufacturing can deliver significant benefits to a medical product commercialization strategy. However, there are variations in contract manufacturing business models and that can impact the value a contract manufacturer is able to provide. 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 the range of services possible, the potential issues that should be discussed during the selection process and the best practices to look for during the audit.

Variation in Contract Manufacturing Business Models

In medical contract manufacturing, the three most popular business models are:

- Manufacturer of engineered components who does larger scale projects through subcontract relationships
- Electronics contract manufacturer who subcontracts production requirements not within their capabilities
- Vertically-integrated, specialty contract manufacturer specializing in design through commercialization solutions

Each of these types of business models can have advantages depending on project requirements.

In the engineered components model, the suppliers may have dominance in specific manufacturing technology such as molding or extrusion. For products that require that technology for the bulk of the product, there may be savings in tooling or design costs. The downside is that design recommendations will center on that supplier's core manufacturing technology and may not include optimization suggestions that involve subcontracted capabilities. Additionally, if the supplier manufactures its own proprietary line of products, those products may have priority for internal manufacturing capacity.

When the product is predominantly electronic, an electronics contract manufacturer may represent the best choice for the project. However, there may be less feedback on optimization choices involving engineered components or only a focus on engineered manufacturing capabilities that the contract manufacturer has in house. Additionally, given the limited redesign capabilities associated with medical products, the options for reducing cost within printed circuit board assembly (PCBA) or the processes associated with the PCBA may be limited.

The vertically-integrated, specialty contract manufacturer typically represents the best option for non-electronic products or electronic products with a significant percentage of engineered components. This is because much of the cost savings in engineered components comes in material and manufacturing technology selection, plus tooling design. A vertically-integrated contract manufacturer can recommend the best manufacturing technology for the product requirements rather than focus on a single core manufacturing capability. Additionally, because tooling complexity/efficiency and unit cost are related,

having the supplier providing those services managing the program ensures that cost reduction focus will be applied in the areas likely to generate the largest savings.

Key Benefits of the Vertically Integrated Model

Given that products benefitting from a vertically integrated model represent the highest level of complexity in terms of supplier interaction at the design phase, this model will be analyzed most closely.

The key benefits can include:

- Reduced time to market
- Enhanced scalability
- Streamlined processes.

Reducing Time to Market

As mentioned earlier, contract manufacturers with one core manufacturing competency and a group of associated suppliers tend to recommend the 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. The expertise to rapidly evaluate multiple technologies reduces both time and cost.

Forefront Medical's new product development process is a good example of how this type of analysis is done. The Company's capabilities include Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems, injection and blow molding, extrusion, metal fabrication, electromechanical assembly, clean room assembly capabilities and packaging. Forefront's design team does have electronic engineering and software development competencies, but sources PCBAs from suppliers specializing in board-level assembly for better economies of scale.

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 biocompatibility 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.

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.

In this example, the expertise of a vertically-integrated contract manufacturer increased design options and opportunities for reducing cost, while shortening the product development cycle.

Enhanced 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 analyzes 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 also utilizes a DDP process for automation design. 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, typically 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 product end markets.

In one example of this phased approach, Forefront's team helped a customer who had developed a patentable concept involving measurement of patient oxygen exhalation, develop a manufacturing strategy that kept tooling and automation cost low until volumes began to increase. 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.

Streamlined Processes

One of the least discussed benefits of the vertically-integrated, specialty contract manufacturer business model is streamlined processes. The more capabilities a contract manufacturer must outsource to suppliers, the greater the number of silos in the manufacturing process. Each of those silos has separate scheduling priorities, which may not align with the contract manufacturer's priorities. Each silo also adds additional markup to the total project cost.

Conversely, a vertically-integrated contract manufacturer can drive priorities across its manufacturing operations. Forecasts and production scheduling are handled through common systems. Freight costs are minimized or eliminated depending on whether the work is done in a single facility or multiple facilities. Less inventory is required as internal production eliminates the transit inventory "pipeline" present when parts are sourced from remote suppliers. When tooling fabrication is included in the capabilities mix, as in Forefront's case, there can be significant reductions in tooling lead-time and

simplified maintenance logistics which translates to decreased downtime when the tool can be serviced in-house.

Selecting the Best Option

In outsourcing, there is no one perfect solution. The best outsourcing processes align customer requirements with partner capabilities. In auditing potential contract manufacturers, questions to ask include:

- How closely do the contract manufacturer's core manufacturing capabilities align with my project?
- How important is product development engineering support to this program?
- Does the contract manufacturer have unique engineering or manufacturing capabilities that are relevant to my project?
- Are there projects of similar type and scope being built by this contract manufacturer?
- Do the contract manufacturer's quality systems and experience with regulatory agencies align with my product's requirements and end markets?
- Has the contract manufacturer solved challenges similar to those likely to happen within my program?
- Does the contract manufacturer's team interact well with my team?
- How does the contract manufacturer identify cost reduction opportunities?
- Do the contract manufacturer's facility locations align with my preferences?
- Does the contract manufacturer have well-defined processes?
- How will my program be managed?
- Does the contract manufacturer offer a similar time zone support option?

Asking questions about the way a contract manufacturer interacts with customer teams, ensures process repeatability, and achieves cost reductions over time ensures unique project challenges are addressed. It also helps better analyze that contract manufacturer's ability to support project requirements. While a quote response provides a comparative datapoint on initial pricing, the deeper exploration of the way each contract manufacturer does business may be more indicative of which one represents the best choice.

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) 830-4637 (Europe and America's) / +86 21 6062 7177 (Asia).