Driving Market Advantage: Six Critical Contract Manufacturer Skillsets

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Optimizing the outsourcing equation involves far more than simply finding a company to manufacture products in an area with low cost wages. A skilled contract manufacturer is expert at product commercialization: eliminating cost and inefficiency throughout design and development phase, offering innovative solutions that provide competitive advantage throughout the product's lifecycle, and delivering a level of quality that enhances brand reputation. The total benefits of this type of relationship go beyond cost savings. They can drive market advantage. The question becomes what skillsets indicate that a contract manufacturer is capable of achieving this level of partnership?

Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, feels there are six critical skillsets that help drive market advantage:

- Scalability
- Cost savings
- Vertical integration
- Quality
- Technology expertise
- Speed.

This whitepaper looks at each of these skillsets and discusses how they contribute to specific areas of market advantage.

Scalability

Transfer of work among suppliers ill-prepared for changes in production volumes can be costly. The COVID-19 pandemic has set manufacturing ramp-up speed records, yet the reverse can also be true. Some products take time to gain market acceptance and need a solution strategically "sized" to likely demand. Similarly, manufacturing solutions need to align with end market logistics even as those requirements evolve. In short, the ability to right size manufacturing solutions and cost effectively support end market solutions is a critical skillset.

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.

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. 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.

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.

Cost Savings

The ability to lower manufacturing-related costs is often a primary motivation for outsourcing. However, in order to achieve the lowest total cost of ownership (TCO) it is important to consider what drives cost in the product commercialization process. Here are some key cost drivers to consider:

- Unnecessary design iterations
- Regulatory hurdles related to materials qualification
- Excessive secondary processing related to poor mold design
- Manual labor in processes that can be cost effectively automated
- Defects related to poor design for manufacturability or lack of process control
- Inefficient logistics
- Poor alignment between tooling choices and projected volumes
- Communications failures between the customer's team and the contract manufacturer's team.

In short, achieving lowest TCO requires a robust process for collaboration in the product development phase. Most unnecessary costs are driven by lack of understanding of the impact of design choices on qualification or manufacturing costs. Consequently, selecting a contract manufacturer able to keep design choices aligned with optimum manufacturability goals will result in larger cost savings.

As mentioned, Forefront Medical's team uses a standardized process for new product development which assesses customer requirements. The result is a DDP, 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.

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 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 unnecessary cost.

Vertical Integration

There are two models in contract manufacturing. One model has a contract manufacturer dominant in a specific manufacturing technology managing subcontracted suppliers who manufacture the product components outside that area of expertise. The other model has a vertically-integrated contract manufacturer whose supply chain is much leaner. Both options are viable. However, the second option eliminates the additional markups and lead-times that are present when a wide range of subcontract component suppliers are utilized. An additional advantage of the second model is that a contract manufacturer expert in multiple manufacturing technologies, will align manufacturing process selection with product requirements, while a contract manufacturer with limited in-house manufacturing capabilities is motivated to recommend their primary area of manufacturing expertise.

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 time-sensitive projects, vertical integration streamlines lines of communication and priorities. 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. There is also more institutional knowledge resident within the team. 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.

Quality

Contract manufacturers aren't simply building their customers' products. They are also strengthening or weakening their customers' reputations with every product shipped. Contract manufacturers focused on superior quality recognize that building quality into products isn't achieved by inspection processes on the production line. It involves eliminating the potential for defects through product design recommendations, process design, optimized automation and training.

Additionally, the rigorous regulatory environment found in the medical device industry drives a need for contract manufacturers to be able to work closely with customers in product and process approval efforts, often for multiple regions. Expertise in this area ensures appropriate procedures are followed and may contribute to faster regulatory approval cycles.

Forefront Medical has a dedicated Regulatory Affairs team whose responsibilities include product registration and CE marking; maintenance of the Device History Record (DHR) and technical file; biocompatibility testing; validation and support sterilization; updates on regulations and communication of new/revised regulations; and intellectual property protection. Forefront's design team provides software verification and validation per industry standards. The team can provide services in electromagnetic compatibility (EMC) testing as per IEC60601 and software life cycle development/documentation as per IEC62304.

All Forefront Medical facilities are registered to ISO: 13485:2016. All facilities are also compliant to MDR 2017/745 which is the Medical Devices Directive for European Community, MHLW Japan's Pharmaceutical Affairs Law (PAL) and Ministerial Ordinance #169. All facilities are FDA and Japan registered as foreign contract manufacturers. Its JiangSu, China facility currently holds an FDA Establishment Registration and Class 2 Product Registered (510k), as well as China National Medical Products Administration (NMPA).

The combination of strong internal process controls, automation expertise and experience with a broad range of regulatory requirements helps ensure product quality and regulatory compliance goals are consistently achieved.

Technical Innovation

While medical device manufacturers are expert at determining what product features their markets need, contract manufacturers are expert at the manufacturing side of the equation. Developing an innovative product often requires an innovative approach to materials choices, manufacturing technology or automation.

Forefront Medical's team continually looks for ways to work smarter. For example, they've pioneered an innovative tool design for sequential molding. Sequential injection molding offers both cosmetic and throughput benefits, but in its traditional form has required a bulky mold and use of larger tonnage machines to accommodate the external hydraulic support system. Forefront Medical's team patented a streamlined sequential tooling design which utilizes a mechanical function inside the tool to eliminate the need for an external hydraulic system. The end result is a tool that easily fits in standard machines of the same tonnage as conventional injection molding tool, but is 50 percent faster than a conventional tool.

Forefront's breadth of vertical integration enables its team to look at a broad range of manufacturing process choices when recommending the optimal manufacturing strategy during product development. They are also expert at making cost saving process improvement suggestions on projects transferred in mid-lifecycle.

Speed

The pressure to reduce time to market has never been greater. At the same time, the mission critical nature of many medical devices combined with the regulatory and legal environment, require that faster development and commercialization efforts include all the checks and balances found in projects run at a slower pace. In short, reducing time to market needs to come from more efficient working environments and a high level of team expertise rather than from skipping steps in the process. This is an area where contract manufacturers can contribute significantly. While product development is a career at most medical device manufacturers, driving efficiency in that process is a mandate at most contract manufacturers. When those two engineering visions are aligned, reducing time to market without sacrificing quality is easily achievable.

In a recent condensed 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), the DDP process discussed earlier helped ensure that all necessary information was transferred and that all key project milestones were incorporated in the DDP.

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.

Leveraging a contract manufacturer's competencies in these six areas is the best way to eliminate unnecessary cost and time from product development, while setting the stage for superior quality production and an optimized logistics strategy. The best way to determine a contract manufacturer's competency in these areas is to ask for examples of ways this expertise has been applied to support projects of similar size and scope.

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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