Rapid Product Development: Four Areas to Audit When Selecting a Contract Manufacturer

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The battle against COVID-19 has created a niche need for companies able to support product development cycles that cut months off traditional product development timelines. Achieving that speed should not translate to abandoning the quality control checks and balances necessary to meet regulatory requirements and achieve superior quality. Like the driver and pit crew relationship in Gran Prix racing, cutting that much time out of a product development cycle requires close collaboration between medical device manufacturer and the contract manufacturer. Everyone needs to understand their roles, project requirements and key milestones. Not surprisingly, selecting a contract manufacturer with well-defined processes, broad capabilities, and significant design and manufacturing expertise can provide substantial advantages in this area.

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 that can help in achieving speed and quality in time-sensitive product development efforts. They are:

- A robust process for ensuring close collaboration during product development
- Internal tooling design and fabrication capabilities
- Vertically-integrated manufacturing capabilities
- Regulatory expertise.

This whitepaper looks at each of these areas and suggests questions for auditing contract manufacturer capabilities in assessing competency.

A Robust Process for Ensuring Close Collaboration

One of the challenges with compressed product development schedules is ensuring that critical information is shared early and that no critical milestones are skipped. When both the medical device manufacturer and contract manufacturer work from established processes, shortening the timeline is much easier to do because both parties can discuss their standard processes and identify the areas where activities can be worked concurrently or compressed.

For example, Forefront Medical's team uses a standardized process for new product development which assesses customer requirements. They then create a Design Development Plan (DDP), followed by a customer specification and collection of market inputs.

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 has helped ensure that all necessary information was transferred and that all key project milestones were incorporated in the DDP. That said, Forefront Medical's full DDP process is designed to provide whatever level of engineering and product development support a customer may desire.

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, 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 on both sides of the equation. 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 combination of strong processes and a broad range of expertise enables Forefront's team to easily customize its approach to support whatever mix of services and expertise a condensed project requires.

Audit questions to ask include:

- Is there a repeatable process in place in for new product development, and if so, what does it typically encompass?
- What capabilities are in place to analyze manufacturability, design assumptions, etc.?
- What existing expertise can be applied to shorten product development timelines?
- If working in different regions, what support is available to make it easier for your team to work in their preferred time zone.

Internal Tooling and Fabrication Capabilities

Tooling for molded parts is often an area that many medical device manufacturing sourcing teams see simply as a line item in non-recurring engineering costs. However, anticipated project volumes, complexity of tool, tooling vendor selection and tool maintenance strategy are all issues that can impact product quality, tooling cost and overall project cost. Additionally, when a contract manufacturer has internal capabilities for tooling design and fabrication, the tooling development cycle can be shortened because third-party fabrication and shipping lead-time is eliminated.

Forefront Medical utilizes a vertically integrated business model, which includes tooling design and fabrication. This vertically integrated perspective ensures that Forefront's team is looking at the big picture rather than tooling choices alone. Their goal is to develop a tooling strategy that meets both cost and development timelines.

In the nasopharyngeal swabs for COVID-19 testing example discussed earlier, 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.

When tooling design and fabrication are integrated into the product development process, tooling options, costs and constraints can be evaluated concurrently with product design decisions. Communication is streamlined, which minimizes time and cost. Forefront Medical enhances this by having standardized software tools in its US Technical Center, Singapore Design Center and China full-scale commercial tool room. Cimatron or NX-Siemens software is used for tool, hot runner and cooling system designs. Mold-flow software is used for mold-flow analysis and to support Design of Experiments (DoEs) to optimize the design and molding parameters when those parameters are not resident in their existing library. Moldex3D software is utilized for molding process simulations to test assumptions prior to tool fabrication. This standardized approach enables tool designers to easily demonstrate the likely performance of the tool under review to the customer's team during the product development process.

Forefront has internal tool fabrication capability, but also works with outside vendors. The team's manufacturing expertise ensures that tooling vendor selection is driven by analysis of the right mix of variables. The team's expertise as a tooling fabricator ensures that when outside vendors are selected, the tooling fabrication process is carefully managed to required specifications.

Forefront Medical also operates a full scale commercial tool room. This provides the resources necessary to maintain tooling on-site. A robust preventive maintenance program that extends the life of each tool, helps minimize unscheduled downtime and contributes to high product quality. Plus, an in-house tool room minimizes the downtime and cost associated with tool maintenance and repair since the tool can stay in the factory instead of being shipped to a third-party tool repair facility.

Audit questions to ask include:

- Does the contract manufacturer have internal resources for tooling design and fabrication?
- Are there interim options such as additive manufacturing to produce products while tooling is in development?
- If third-party suppliers are used for tooling development and fabrication, does the contract manufacturer have internal engineering expertise to manage that process?

- Does the contract manufacturer have the internal resources to provide tool maintenance on-site?

Vertically Integrated Manufacturing Capabilities

Product cost, feel, functional capabilities, ease-of-use, biocompatibility, patient comfort, industrial design, compatibility with other devices and quality are sources of competitive advantage. Often these aspects of competitive advantage require work with specialized materials. While a "full-service" contract manufacturer that specializes in one manufacturing technology such as molding or extrusion can manage subcontracted suppliers, the range of choices in terms of technology and materials may be far more limited than found with a vertically integrated, full service contract manufacturer. 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.

Audit questions to ask include:

- What production capabilities are resident in-house at the contract manufacturer vs subcontracted to outside suppliers?
- Do the contract manufacturer's in-house capabilities align with project requirements?
- Does the contract manufacturer have sufficient capacity to address the initial production timeline and quantity needs on time sensitive projects?
- Are there capabilities resident in one contract manufacturer that will clearly provide a speed advantage?

Regulatory Expertise

One of the most costly aspects of medical device manufacturing is meeting the regulatory requirements of different markets. 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).

Audit questions to ask include:

- Does the contract manufacturer's regulatory support team have the expertise to identify issues that need to be addressed early in the development cycle?
- Can the contract manufacturer support the necessary validation efforts?
- Does the contract manufacturer have existing relationships that can help streamline regional approval processes?

The Forefront Medical Advantage

Forefront Medical has the capabilities to support a broad range of medical products from single use to electromechanical devices.

Forefront Medical Technology's Singapore Engineering Design Center supports micro molding, specialty catheter production, rapid prototyping, product development and tooling fabrication for complex molds. The Engineering Design Center's capabilities include product development engineering for precision-engineered and electromechanical products. Software development engineering is also available. The Singapore manufacturing facility is focused on advanced technology products such as implantables, tissue fasteners and micro-molded devices or parts. It is also a good solution for smaller footprint pharma devices such as implantable drug delivery systems. Facility capabilities include rapid prototyping (SLS) systems, molding, and mechanical and electromechanical assembly. While Singapore's labor costs are higher than those of China, where Forefront also has manufacturing facilities, Forefront's expertise in production automation contributes to increased Singapore manufacturing cost competitiveness by significantly reducing manpower as projects increase in volume.

The contract manufacturing industry has a range of business models from limited support "build to print" to full service, vertically integrated manufacturing partners. When speed is part of the equation, selecting a contract manufacturer able to add product commercialization expertise is critical.

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 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).