On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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Rapid Product Development: Four Areas to Audit

Forefrant's vertical integration provides advantages in rapid product development and commercialization.

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 Grand Prix racing, cutting that much time out of a product development cycle requires a close collaboration between the 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 feels there are four areas that can help in achieving speed and quality in time-sensitive product development efforts.

A Robust Process for Ensuring Close Collaboration

One of the challenges with compressed product development schedules is ensuring that

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2020 – A Year of Challenges and Accomplishments

Walter Tarca

As I write this, COVID-19 vaccines are in distribution around the world helping to set the stage for a return to more normalcy in 2021. This past year has been challenging throughout the world. The virus has killed over 1.6 million people and directly impacted the lives of tens of millions. When the economic consequences are considered, the impact is far broader. That said, looking at 2020 simply as a year of great tragedy overlooks the accomplishments of those who overcame the challenges put in their path. Healthcare workers, researchers, drug companies, device manufacturers helped to change the playing field this year. In our organization, employees at all levels stepped up to address the necessary challenges to adapt their family and work life routines, learn new skills and support our rapid response in producing COVID-19-related projects.

Early in the year, our teams in China and Singapore successfully navigated the initial COVID-19 shutdowns and travel restrictions, returning to full operational status by March 9th. Facility expansion investments we began making in Singapore in 2018 proved prescient earlier this year when we were able to utilize our additional clean room capacity,

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Areas to Audit

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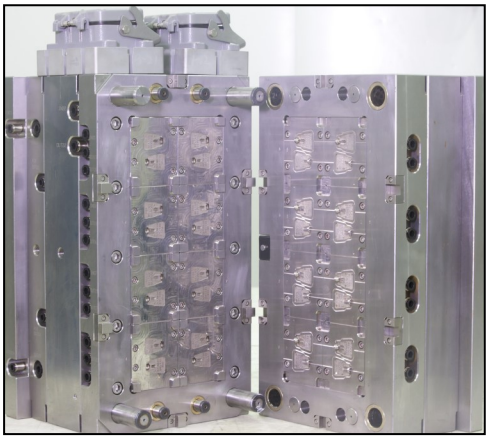
critical information is shared early and that no critical milestones are skipped. When both the medical device manufacturer and contract manufacturer work from established processes, shortening the timeline is much easier to do because both parties can discuss their standard processes and identify the 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.

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?



Forefront Medical's team can design and fabricate molds in-house or work with third-party suppliers.

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.

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. 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" con-

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Reflections on 2020

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additive manufacturing capabilities, technical support and automation to partner with Singapore's R&D community and associated medical device manufacturers in developing products supporting COVID-19 mitigation efforts.

I am particularly proud of our team's effort to support the National University of Singapore (NUS) development effort related to nasopharyngeal swabs for COVID-19 testing. The project started in May 2020 and we shipped 1 million 3D printed swabs in July 2020, which passed all acceptance tests. An additional 10 million injection molded swabs will be delivered over the next 15 months. We've also been involved in additional projects from test kit reagents to personal protective equipment (PPE) in our various operations around the globe.

As we enter 2021, I'm enthusiastic about our direction. We continue to broaden our portfolio of manufacturing capabilities and are now challenging our team to further raise the bar in the realm of continuous improvement processes. We build our vision based on a value set derived from listening to the voice of our customers. These core values are:

- Quality performance
- Integrity
- Innovation
- Customer focus
- Continuous improvement
- Accountability.

In the coming year we will share more about the ways Forefront is continuing to evolve to better align with the equally evolving needs of our customer base. I'd like to wish everyone a happy holiday season and a healthy and prosperous 2021.

Areas to Audit

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tract manufacturer that specializes in one manufacturing technology 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. 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.

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 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.

On the FOREFRONT

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Forefront Medical Technology focuses exclusively on the medical device industry and thoroughly understands the needs of this market. As a specialty contract manufacturer with a focus in disposable diagnostic, drug infusion and medical device systems, Forefront Medical has extensive expertise with injection molding, extrusion, assembly and packaging of specialty medical disposable devices. In addition, Forefront Medical Technology's technical expertise extends into collaborative product design and development, rapid SLS prototyping, in-house tool making and isolated clean rooms for manufacturing, assembly and packaging. Capabilities also include sterilization and global logistics to provide one integrated source for the total supply chain. This world class supplier has the expertise to custom design a new product… or redesign the current one…from a conceptual drawing into a completely manufactured, packaged and sterilized product, ready for global shipment.

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Forefront Medical Launches Innovative Covid-19 Test Swab

Forefront Medical Technology is now selling a COVID-19 test swab which it manufactures in Singapore.

EZYSWAB's patented design offers patients and caregivers the best of both worlds: the flexibility of biocompatible nylon for ease of nasopharyngeal insertion and a Safe Break Point feature facilitating quick transfer to a sample collection tube.

The swab's flexibility combined with its Safe Break Point feature, also minimizes the risk of accidental breakage during the nasopharyngeal insertion procedure.

The swab tip's unique design has been clinically-proven to be effective in collecting samples for PCR testing in both clinical trials and laboratories. When compared with a rigid swab, EZYSWAB's flexible design received higher patient comfort ratings.

EZYSWAB is individually-packaged to maintain sterility and ease-of-use.

Currently, average delivery time is 14 days and the product has a 3-year shelf life.

Additional information and an inquiry form is available here.