The Benefits of Outsourcing with A Full Service Contract Manufacturer

November 21, 2019

Contract manufacturers serving the medical device market typically divide into two distinct segments: electronics contract manufacturing and precision engineering contract manufacturers. Electronics contract manufacturers build both printed circuit board assemblies (PCBAs) and electromechanical systems. Precision engineering contract manufacturers focus on non-electronic products requiring molding, metal fabrication, extrusions or other custom components. There are distinct skill sets in each type of supplier. Electronics contract manufacturers are typically experts in the assembly and test issues related to PCBAs and associated box builds. Precision engineering contract manufacturers are expert in tooling development, materials qualification and assembly automation.

The reasons these distinct supplier segments exist is because medical devices segregated neatly into each segment. However, as electronics become more pervasive there is more convergence. One good example of this is drug delivery systems. The dispensing mechanism is electromechanical, but there is also a substantial amount of tubing and disposable components associated with the system.

A core benefit of either type of contract manufacturer is access to shared resources of production at a fraction of the cost of developing that production infrastructure inhouse. Customers pay for the shared machine time they use instead of having to absorb the full costs of inhouse equipment they may not be fully utilizing.

The disadvantage of segregating contract manufacturing services to either electromechanical or precision engineering disciplines is that creates silos in the product development phase, increases complexity of the supply chain and may add redundant cost structures or markups to the final assembly and fulfillment process.

Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, believes that offering both electromechanical and precision engineering services is fundamental to achieving lowest total cost of ownership in contract manufacturing. In the drug delivery system example discussed above, the ability to address both the electromechanical, tubing and disposable component elements of the equation enables customers to leverage synergies throughout the product development and commercialization process. This whitepaper looks at the benefits of this type of full service outsourcing approach in terms of product development, regulatory considerations, supply chain management, production and assembly processes, and fulfillment.

The Product Development Phase

The robustness of a contract manufacturer's process for supporting the commercialization of new product or a smooth transfer of work has direct impact on time to market, quality and cost. When this development effort is managed by a single supplier instead of in silos at multiple suppliers, it ensures that all opportunities for reducing cost and ensuring optimum quality are considered.

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. A customer specification is then developed and market inputs are collected.

On the custom parts side of the equation, once the customer specification is approved, 3D CAD models are developed and analyzed. 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.

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 also 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. As the Company is headquartered in Singapore, where English is considered the language of business, its 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. Additionally, the Singapore location performs specialty manufacturing and prototyping, making it an ideal support location for OEM R&D teams located in Singapore's growing hub of medical innovation.

Regulatory Support

One of the most costly aspects of medical device manufacturing is meeting the regulatory requirements of different markets. Often, the cost driver isn't in established systems, but instead in the regulatory requirements learning curve found in new markets. Working with a contract manufacturer capable of supporting a global device marketing strategy in terms of validation testing and quality infrastructure saves time and improves economies of scale. When silos are eliminated by having one contract manufacturer manage this element of the product development process, the time line and overall process efficiency is optimized.

In addition to money saved by selecting a manufacturing partner with regulatory expertise and the appropriate quality system registrations, there may also be efficiencies found in their relationships with regulatory agencies. Contract manufacturers who regularly work with the agencies relevant to your products represent a known supplier to those agencies and understand the best contacts for addressing any issues that may arise. 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 MDD 93/42/EC which is the Medical Devices Directive for European Community, MHLW Japan's Pharmaceutical Affairs Law (PAL) and Ministerial Ordinance #169, ISO 15378 which is focused on primary packaging materials for medicinal products. 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 FDA (CFDA).

Supply Chain Management

A key benefit of a full service approach to contract manufacturing is optimization of the supply chain. Forefront's level of vertical integration helps simplify the supply chain by ensuring that many of the fabrication and assembly processes are done in-house. That said, Forefront's supply chain management team ensures that materials and products not cost effective to manufacture in-house are sourced from cost competitive, superior quality suppliers.

Production and Assembly Processes

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.

Forefront Medical's in-house capabilities include tooling design and development, injection molding, micromolding, blow molding, extrusion, machining and box build electromechanical assembly. This combination of capabilities benefits its customers in four ways. First, in design projects the engineering team matches the best process to the product requirements since there are range of production capabilities to choose from in-house. Second, this level of vertical integration streamlines the process and centralizes accountability for project success. Third, vertical integration reduces costs and logistics complexity. The larger the supply chain associated with that contract manufacturer, the more markups and added costs are rolling up into the price. Finally, vertical integration also contributes to intellectual property (IP) protection, which reduces the potential costs of loss of market share and the legal costs of defending intellectual property. Often IP theft occurs not at the manufacturer building the outsourced product but at smaller suppliers building a large enough portion of the product to see a large amount of documentation.

Fulfillment and Logistics Expertise

Logistics management is a key part of reducing total cost of ownership. A contract manufacturer's expertise in regional supply chain identification plus an ability to determine the best shipment strategy for support of the end market can provide substantial savings.

Forefront Medical's team has significant experience optimizing logistics costs. Its facility locations have been selected for their proximity to major shipping hubs and support infrastructure such as contract sterilizers.

Centralizing box build production in a single facility helps minimize inventory and reduce shipping costs.

Selecting a contract manufacturer vertically integrated enough to be able to support the entire product commercialization process eliminates redundant costs, reduces required inventories, optimizes logistics and increases production schedule flexibility.

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.

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