Do Your Contract Manufacturer's Capabilities Support Your Manufacturing Regionalization Strategy?

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Regionalized outsourcing strategies continue to grow in popularity. Gone are the days of shifting outsourcing to the lowest cost emerging market location. Today, most companies base sourcing strategies on a complex equation of factors driving total cost. When all these factors are considered, locating manufacturing within regions close to each end market often results in the greatest degree of responsiveness to market demand and lowest total cost. The underlying logic behind any regionalization strategy is that proximity to the end market reduces logistics costs and complexity; reduces raw material and finished goods shipping time; decreases finished goods safety stock requirements; and contributes to superior quality by minimizing unnecessary handling, transport and inspections.

The question becomes: can the contract manufacturer your company selects enable your company to leverage the benefits of a regionalization strategy in your chosen end markets?

In this whitepaper, Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems highlights several areas to evaluate in determining whether or not a supplier's capabilities are likely to deliver lowest total cost of ownership (TCO):

- A robust process for New Product Introduction or Transfer of Work
- Local support in your team's home region
- A vertically-integrated business model to more efficiently provide a seamless product commercialization solution
- Supply chain management expertise
- The logistics expertise to minimize distribution costs
- A strong quality infrastructure capable of supporting global regulatory requirements
- Ability to provide support in better accessing end markets.

New Product Introduction and Transfer of Work

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. From an audit standpoint it is best to look for evidence of strong processes, internal support infrastructure and experience with projects of similar size and scope.

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. 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.

In a transfer of work process or "lift and shift" strategy that introduces existing product lines to new markets or improves quality through a change in contract manufacturers, Forefront Medical's team not only has a standardized process for the transfer, but also works to add value to the transfer process. For example, when a manufacturer of enteral feeding tubes wished to transfer their production line from New Jersey to one of Forefront Medical's facilities in Asia, a dedicated project team completed the transfer in four months. Their process included developing/executing a plan for supply chain continuity; risk management; machine, tools and process validation; product bio-compatibility and stability validation; sterilization validation including sealing integrity; and packaging ship testing. Kaizen events were used to improve the process over time. Additionally, its engineering team made recommendations for enhanced product design and quality.

Proximity to Your Local Team

Just as proximity to the end market simplifies handling and logistics, proximity to the customer design team simplifies communication. Many of today's engineers seek work-life balance. Long hours at the office to facilitate distant time zone communication or frequent trips overseas to manage a distant supplier face-to-face can drive personnel attrition. Forefront Medical operates a U.S. Technical Center to make it easier for U.S. customers to communicate with their personnel in a time zone convenient to their normal work schedule.

Additionally, 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.

A Vertically Integrated Business Model to More Efficiently Provide Commercialization Support

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. It can also create situations where there is frequent blame shifting on quality issues, making it difficult to find and eliminate the root cause. 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. In this model, the contract manufacturer manages any subordinate supply chain, taking responsibility for ensuring accurate communication and elimination of any issues that may arise.

Forefront Medical's in-house capabilities include tooling design and development, injection molding, micromolding, blow molding, extrusion, machining and 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.

In addition to its Singapore headquarters, Forefront Medical Technology operates two manufacturing facilities in China. The facility in Xiamen, PRC is primarily focused on production for export to other regions. The facility in Changzhou, PRC was added to support customers requiring a source of domestic production for China and or export, with an economic proximity to their R&D centers in Shanghai.

Forefront Medical is also committed to helping its customers realize a competitive commercialization strategy over time. To that end, its engineering team utilizes a continuous improvement value-added process to identify opportunities for cost reduction and/or improvement in the overall total product cost by evaluating internal processes and surveying end users. Internally the focus is on identifying production bottlenecks and long lead-time issues, and includes feedback from operators and technicians. Externally, the focus is on ease-of-use. The team develops a list of potential improvements and then selects the top priorities. A timeline is developed and progress is tracked.

The project is closed once 80-90% of the improvements have been achieved. This process varies from a traditional Value Analysis Value Engineering (VAVE) process in that VAVE projects tend to be completely cost-driven. In this process, the goal is to eliminate non-value added cost and increase market share.

Supply Chain Management Expertise

Supply chain rationalization in combination with a regionalized outsourcing strategy can pay large dividends with a supplier capable of managing production of the complete product. Contract manufacturers with the supply chain management expertise who can identify superior quality, cost competitive suppliers and assist in the qualification and validation process, help lower the TCO significantly.

For example, Forefront Medical was supplying a customer with infusion lines used in a drug delivery system. The bags used with infusion lines were supplied by two manufacturers in Europe. Forefront's team suggested to the customer that sourcing the entire set of four bags and infusion lines in Asia with

Forefront could eliminate redundant logistics costs, increase visibility into inventory levels, improve quality and reduce production costs. The new process reduced total cost of the set by 22%. The primary driver of cost savings was reduction in transportation and inventory costs. In the original model, raw roll form material was being shipped to two European manufacturers. Forefront Medical was shipping infusion sets to these manufacturers, as well. The manufacturers were then shipping final product to the customer. Raw material and finished goods inventory was spread over three suppliers. This increased the number of transactions the customer's supply chain management personnel needed to manage, plus made it more difficult to maintain real-time visibility into raw materials, work-in-process and finished goods inventory status.

Today, the customer's team places orders with Forefront Medical. Forefront's team manages the raw material supply base and optimizes ordering and stocking practices to minimize transportation and inventory carrying costs. The complete set ships to the customer.

Logistics Expertise

Logistics management is a key part of reducing TCO and a contractor'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 in supply chain realignment to reduce logistics costs. Its facility locations have been selected for their proximity to major shipping hubs and support infrastructure such as contract sterilizers.

For example, Forefront's Xiamen, PRC facility is located in the Xiamen Export Processing Zone. Xiamen was one of the first four special economic zones (AEPZ) in China and one of the few municipalities enjoying independent status in state economic planning. Xiamen is located on the southeastern coast of China, to the west of Taiwan Strait. This location has made it one of the most important ports in China for international trade and cross-Straits trade.

Changzhou, PRC provides both logistical and tactical advantages. The facility is located in the Jiangsu Wujin Economic Zone, where there is a designated medical technology park, known as the West Taihua Lake International Medical Industrial Park, which is in close proximity to medical clusters in Shanghai and Suzhou.

There is a globally renowned sterilizer in Suzhou and a China FDA office in the park. The park is located within 25 kilometers of local air and seaports, plus near the Yanjiang highway, which is the one of the main routes between Nanjing and Shanghai. Changzhou University Town is also near the park and features six schools that support the region's vocational training needs. Additionally, Changzhou is located in one of China's 'green' special economic zones. Companies in this zone are subject to more stringent regulation in terms of environmental regulations, and worker health and safety practices.

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. Conversely, when an OEM team provides that service and must bring the new contract manufacturer's processes up-to-speed, internal costs increase.

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.

All Forefront Medical facilities are registered to current revisions of ISO 9001 and ISO: 13485. 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, ISO 14001 which is focused on environmental management, ISO 18001, which is focused on occupational health and safety management, and ISO 27001, focused on information security management. All facilities are FDA and Japan registered as foreign contract manufacturers. Its JiangSu, China facility currently holds a FDA Establishment Registration and Class 2 Product Registered (510k), as well as China FDA (CFDA).

Ability to Provide Support in Better Accessing End Markets

While some contract manufacturers have facilities in low cost labor markets, they don't always have strong business relationships within the end markets.

Asia is home to half of the world's population and a combination of mature and emerging economies with a growing and aging middle class. A 2014 article in Medical Device and Diagnostic Industry titled, "ASEAN Countries Could Be the Next Emerging MedTech Markets," highlighted that with Southeast Asia's increasing wealth came an increasing number of lifestyle-related chronic conditions and diseases more commonly found in the West such as diabetes, orthopedic problems, cardiovascular disease and cancer.

Forefront Medical Technology is headquartered in Singapore and has been an active participant in medtech growth initiatives within the region. Its network of relationships and expertise in the market can help clients less familiar with the region better align their marketing and distribution efforts to take advantage of regional incentives and efficiencies.

Singapore serves as both a regional medtech R&D and financial hub within Asia. According to the Singapore Economic Development Board, more than 30 global medical technical companies are carrying

out research and development efforts related to technology and product development in Singapore. It has become a regional hub of innovation because of its combination of ethical business-friendly practices, strong research and educational institutions, and geographic advantages logistically.

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 and packaging.

Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485, ISO 9001 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 www.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) / +86 021-5175 1516 or +86 021-5175 1513 (Asia).