Case Study: Eliminating Hidden Costs in Outsourcing

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Outsourcing discussions often focus on manufacturing capabilities or regional labor costs. However, that narrow focus often allows hidden costs related to transactional redundancies and other inefficiencies to slip in.

In addition to lowering the labor cost and eliminating the need for investment in plant and equipment, outsourcing to a full service contract manufacturer frees up working capital, by eliminating the need for money to be tied up in raw material and work-in-process inventories. The contract manufacturer typically purchases material and carries the costs of production during the conversion cycle, billing the OEM as product ships. Administrative transactions are reduced since the contract manufacturer manages the bulk of the supply chain. There may be additional savings in overhead personnel as contract manufacturer resources eliminate the need for large manufacturing support organizations. If logistics are optimized, unnecessary transit legs may be eliminated. In short, when the value stream is optimized, many unnecessary, hidden costs are eliminated and throughput increases. In this case study, Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems discusses the ways that changing the manufacturing strategy for a specialty drug infusion set reduced cost and improved overall quality.

The Challenge

A medical device manufacturer with distribution points in the U.S. and Mexico, originally felt that having specialty drug infusion kits manufactured in Mexico represented the lowest cost solution due to the assembler's low cost of labor. The OEM continued to purchase material and packaging and ship to the assembler. While the assembly cost was an improvement over manufacturing cost internally, the OEM was continuing to carry the administrative and inventory costs associated with supplying raw material and packaging.

The Solution

Forefront Medical Technology proposed a turnkey production solution utilizing its production facilities in Changzhou, PRC and Singapore. The Singapore facility's production enabled the OEM to take advantage of Singapore's preferential trade agreements with the U.S. for products that would otherwise be subject to tariffs or ineligible for sale to government entities. Singapore has 20 implemented FTAs with 31 trading partners, including the U.S. and the E.U. In addition to tariff mitigation, the Singapore Free Trade Agreement with the U.S. (SGFTA) also qualifies it as a "designated country" under the Trade Agreements Act of 1979 (TAA). As a result, products qualifying as Singapore origin under SGFTA can be sold as TAA-compliant, which can be important for products sold to U.S. government entities such as the Veteran's Administration. Products made entirely in China are not TAA-compliant.

Forefront's team was able to identify a cost competitive supply chain within Asia to support both production sites. Its engineering team also developed an automated production line strategy. The

project had monthly volumes exceeding a million units and there were 150 different product configurations. Seven automated assembly lines were built to accommodate production requirements.

Sterilization was performed at the customer's global distribution and sterilization facility. The products are then shipped to the OEM's warehouses in the U.S. and Mexico for either distribution directly to end markets or incorporation in larger kits. In cases where OEMs do not have their own sterilization capability, Forefront's team can manage sterilization via contract sterilizers located near each production facility. Both ethylene oxide (EtO) and e-beam options are available.

The Result

In this case, changing the strategy provided the OEM with multiple benefits:

- Elimination of raw material purchasing administrative workload
- Reduction in required working capital
- Reduction in overall raw material costs
- Reduction in overall administrative transactions
- Reduction in administrative transactions
- Optimized logistics.

Additionally, the automation strategy significantly reduced production headcount while improving quality, since automated processes eliminate the variation than can occur in manual assembly processes.

Key Forefront Medical Technology Advantages

Robust Transfer of Work Process

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.

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. The process includes 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.

Most importantly, Forefront's team understands the importance of flexibility in supporting evolving customer requirements. Its team's expertise, strong transfer of work process and use of simulation software can help identify many potential issues before they create significant cost issues. Additionally, Forefront has a track record of efficiently supporting projects with evolving requirements.

Multiple Facilities to Provide Redundancy and Trade Agreement Access Flexibility

Forefront Medical Technology operates multiple facilities within Asia. This internal redundancy adds additional resiliency to customer strategies looking to mitigate supply chain disruption risk or utilize preferential trade agreements.

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. Use of common software, equipment platforms and processes ensure redundancy in the event of a natural disaster.

Strong Focus on Cost Reduction and Product Enhancement

The customized tooling and automated processes associated with single-use medical products typically drive the need to sole-source products, often for the life a product.

Forefront Medical 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.

Logistics Expertise

Logistics management is a key part of reducing total cost of ownership when adding an additional manufacturing source in a different region. 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 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.

Vertical Integration

Vertical integration streamlines 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 product design, tooling design and development, injection molding, micromolding, blow molding, extrusion, machining and both mechanical and 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.

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 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).

To fully access the cost reduction benefits of outsourcing, finding a contract manufacturing partner capable of seamlessly integrating into the product commercialization process is critical. That alignment should include product development and/or transfer support, product and process validation support, logistics optimization and a focus on cost reduction over the life of the project in addition to manufacturing expertise and labor cost advantages.

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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