

On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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Case Study: Reducing Cost While Improving Quality

Inefficiencies in the outsourcing process can add significant cost. In this case study, Forefront Medical Technology 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
- Optimized logistics.

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



Forefront's vertical integrated capabilities optimize outsourcing strategy.





Reducing Total Cost by Optimizing the Value Stream

Outsourcing discussions often focus on manufacturing capabilities or regional labor costs. However, that narrow focus can allow 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. Here are some of the key elements that Forefront Medical Technology brings to this equation:

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

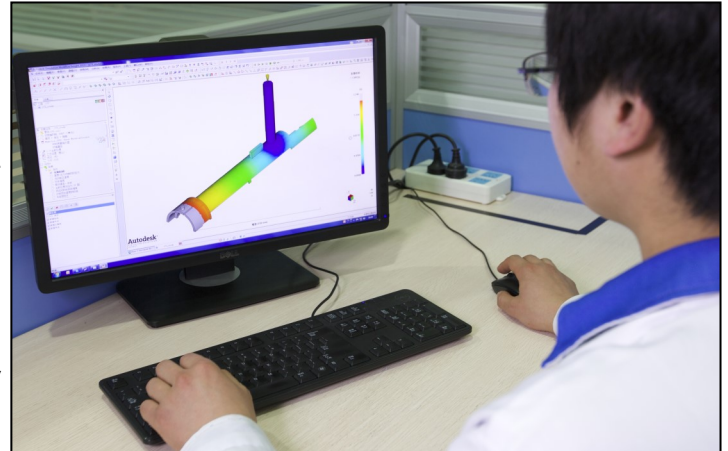
quality through a change in contract manufacturers, Forefront Medical's team not only has a standardized process for the transfer, but also works to add value to the transfer process. The process includes developing/executing a plan for supply chain continuity; risk management; machine, tools and process validation; product biocompatibility 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 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 pro-



Forefront's engineering team focuses on manufacturing efficiency.

duction 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. Its wholly-owned U.K. operation can also provide specialized contract manufacturing services within that region.

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 of 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. Inter-

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Optimizing the Value Stream

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nally 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 recommenda-

tions 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:

- The best process can be matched to the product requirements since there are a range of production capabilities to choose from in-house
- The process is streamlined and accountability is centralized
- Cost, overall markups and logistics complexity are reduced
- Intellectual property (IP) is better protected since the supply chain is smaller.

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



Forefront vertically integrated operations include significant molding capability.

terms of validation testing and quality infrastructure saves time and improves economies of scale.

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).



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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.

USA: Business Development & Technical Sales Office

Farmington, CT 06034-1234

Phone: (860) 255-7610

www.forefrontmedical.com

Forefront in the News

Forefront Medical Technology is continuing to invest in new capabilities and technologies to better serve its medical customer base.

Arrow Medical Limited is now a wholly-owned subsidiary of Forefront Medical Technology. Arrow Medical is a U.K. medical contract manufacturer specializing in textiles, RF welding, silicon injection molding and clean-room assembly. This provides a manufacturing footprint within the U.K. when close proximity to the U.K. or Europe is desired. Its facility includes three ISO Class 7 (US Fed Std 10,000) clean room assembly facilities for the assembly of single use devices and other Class 2 and Class 3 products for use in anaesthesia, emergency and cardiac treatments. Two additional clean room facilities are dedicated to High Consistency Rubber (HCR) and liquid silicone



Arrow Medical Limited is now a wholly-owned subsidiary of Forefront Medical Technology.

rubber (LSR) moulding and RF welding, respectively. Currently, Arrow is helping in the fight against COVID-19 by using its medical fabric assembly capabilities to produce PPE gowns for UK hospitals.

Forefront's President Walter Tarca has recently been interviewed in both Medical Product Outsourcing and the Singapore Straits Times on its investment in

capabilities expansion which include:

- The additional of electromechanical design and assembly capabilities
- Investing S\$1.5 million to update and expand cleanrooms, enhance automation capabilities and diversify its talent pool within its Singapore headquarters facility
- Focus on additional technologies such as 3D-printed nasal swabs and in vitro diagnostics.

The Medical Product Outsourcing article related to outsourcing trends is available [here](#).

The Singapore Straits Times article highlighting Forefront's investments is available [here](#).