

Case Study: Reduced Cost Through Supply Chain Realignment

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Overview

Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, 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 customer had been pleased with Forefront Medical's performance on the infusion lines and agreed to the transfer the entire project.

The Challenge

The key challenge was ensuring the transfer of work and subsequent validation process was handled as efficiently as possible, since an inefficient process can eliminate any near-term cost savings. From a transfer perspective, Forefront's team needed to identify a qualified source of roll form raw material for the bags, transfer and enhance the process to eliminate quality issues that were occurring at the previous suppliers and support process validation and regulatory approvals.

The Process

Forefront's materials team determined that the optimum supplier of the roll form material used in the bag was in The Netherlands.

From a manufacturing standpoint, the critical process involved sealing the infusion port on the bags. In use, the bags are pressurized and seal integrity must be maintained. Forefront's engineering team designed an automated manufacturing and sealing process, plus the appropriate pressure tests to validate seal integrity. The process was validated on schedule. The sets are in production in Forefront's Jiangsu, China facility.

Forefront Medical's dedicated Regulatory Affairs team helped ensure an efficient and rapid validation process. Expertise in global regulatory issues is critical in ensuring that this type of transfer of work is completed as quickly as possible. A key part of Forefront Medical's partnership equation is its robust approach to ensuring superior quality and compliance with relevant regulatory processes. The team is charged with supporting 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.

The Company's investments in strong quality infrastructure were also beneficial. All Forefront Medical facilities are registered to ISO 9001:2008 and ISO: 13485:2003. 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). Having this breadth of quality certifications and registrations in place, plus the concomitant relationships with the approving bodies also contributes to an efficient project transfer.



The Result

The new process reduced total cost of the set by 40%. 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.

This case study illustrates the value of not only considering unit cost. Supply chain rationalization in combination with a move to a lower cost region can pay large dividends with a supplier capable of managing production of the complete product. In this situation, the customer had an established relationship with Forefront which provided the reassurance that the Company was capable of meeting the required quality levels.

About Forefront Medical

Forefront Medical 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, Farmington, CT USA and Riel, Netherlands 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 implantable PEEK micro-molded components, laryngeal mask airways, diagnostic devices, drug delivery systems, enteral feeding and multi-lumen 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://www.forefrontmedical.com/enquiry.html>, email us at: appl_dev@forefrontmedical.com, or call +1 (860) 255-7610 (Europe and America's) / +86 21 5175 1516 (Asia).