FOREFRONT

Outsourcing Best Practices Series

Issue 4

Will Migrating Your Project to a Lower Cost Region Lower Your Total Cost?

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Medical device manufacturers face continuing challenges to reduce cost without lowering quality. At the same time, a key benefit of globalization has been the emergence of health care market growth opportunities as the quality of medical care improves in densely populated emerging markets such as China and India. These trends drive many companies to reassess their manufacturing and supply chain choices.

To understand whether or not migrating a project to a lower cost region will save money, it is important to look at total benefits of that move. Labor cost differences alone may often not be enough to justify the transfer, since medical devices are often manufactured in highly automated environments. However, when lower labor cost is combined with other synergies such as proximity to emerging growth markets or the bulk of your supply chain, the cost equation often makes sense.

A conversion from in-house manufacturing to outsourcing may also improve the cost equation, by tapping the resources of a company already resident in the chosen region. This can eliminate learning curve, improve inventory turns, reduce internal transaction costs and simplify logistics, in addition to lowering labor cost. The key is finding a partner with the resources in place to minimize transfer cost and complexity, who also aligns well with the goals driving the migration strategy.

Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, frequently helps its customers determine whether or not migration of existing production to China makes sense for their products. There are four critical elements that must be supported in order to have a successful migration:

- The contract manufacturer must be able to support regulatory requirements
- The contract manufacturer's team must be able to document the existing process and replicate it
- Communication among teams should be clear and convenient for the customer
- The contract manufacturer should take a proactive approach to cost reduction suggestions

In short, the goal shouldn't simply be to migrate to a lower cost region and then upgrade the contract manufacturer to your company's standards, since the costs associated with that effort eliminate much of the savings. Instead, the goal should be to find a manufacturing partner in a lower cost region with a proven track record of meeting its customers' needs.

The Regulatory Environment

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. Most disposable medical products require high levels of automation and customized tooling, which can make selecting multiple suppliers to serve

different regions less cost competitive. 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, having your team provide that service and bring the new contract manufacturer processes up-to-speed on the requirements relevant to your products' markets will likely adds more cost than the migration saves.

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 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)

Efficient Project Transfer

Most companies do not measure project transfer cost accurately. While non-recurring engineering costs, tooling and any new automation costs are easy to measure, the costs of the team managing the transfer and learning curve mistakes are typically not measured.

If the project has been previously outsourced, there will likely be good process and product documentation. However, when projects move from internal manufacturing to a contract manufacturer, there is often institutional knowledge that does not get automatically transferred. Having a partner with the manufacturing and engineering skills necessary to assess, document and transfer the process can save significant amounts of money. Since fielding the team to manage the transfer is the contract manufacturer's responsibility, the customer easily saves several thousand dollars per week in combined travel cost and personnel time. Forefront Medical realizes that speed and accuracy of transfer can make or break the cost savings equation. Their engineering team views processes onsite and then validates all documentation to ensure that it is accurate and includes all necessary information.

Efficient Communication

Communication is another area where the potential costs of inefficiency are not clearly understood. While the most obvious example, would be the cost of errors made due miscommunication driven by language differences, there are many softer costs. When there are significant time differences driven by

distance, your team may experience higher attrition related to frequent overtime and/or travel required to communicate with the contract manufacturer's team.

Forefront Medical 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, it 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.

A Proactive Approach to Cost Reduction

As mentioned earlier, due to the customized tooling, automation and processes associated with manufacturing disposable medical products, it isn't unusual to sole-source manufacturing. And, while a manufacturing migration may make sense to support large shifts in primary markets or location of the bulk of the supply chain on a long-lifecycle product once, it rarely makes cost sense to do it more than once. Yet, cost pressures continue. So, it becomes important to find a supplier who not only offers an initial improvement in cost structure, but who also has processes in place to drive continuing cost reduction over the life of the product.

To support this challenge, Forefront Medical developed a continuous improvement value-added process to identify opportunities for cost reduction and/or improvement in the overall competitiveness of the products it produces 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 the customer's market share.

Conclusion

Migrating products to a lower cost region can save money. However, when evaluating and selecting potential suppliers, careful attention should be paid to the ability of that supplier to efficiently manage the transfer and provide appropriate levels of support. Selecting a qualified, full service contract manufacturer can reduce both measurable and hidden cost.

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 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://www.forefrontmedical.com/enquiry.html, email us at: appl_dev@forefrontmedical.com, or call +1 (860) 255-7610 (Europe and America's) / +86 21 6062 7177 (Asia).