FOREFRONT

Outsourcing Best Practices Series

Issue 6

Five Mistakes to Avoid in Outsourced Program Transfers

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Introduction

Transferring the manufacturing of medical disposables from one part of the world to another poses unique challenges given the combination of a robust regulatory environment, and custom tooling and automation. That said, when done properly, a 'lift and shift' strategy can seamlessly achieve its goals.

Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems, frequently helps its customers transfer production to its facilities in China in a cost-effective manner. This paper looks at mistakes made in poorly-planned program transfers. The five most common are:

- Failure to fully define the desired outcomes of the transfer
- A focus on price instead of considering the total cost
- Poor understanding of available supplier capabilities in the preferred transfer region
- Lack of a robust transfer plan, and
- Unanticipated regulatory issues.

Failure to Fully Define the Desired Outcomes of the Transfer

Often, a significant issue such as a cost reduction imperative may be the primary reason for a need to transfer the program. With the right manufacturing partner, a program transfer can accomplish much more than simply reducing labor cost. Issues to consider in determining desired outcomes include:

- Does the product need to be redesigned to address competitive challenges?
- Is the current manufacturing process meeting goals for quality?
- Are there identified inefficiencies in the current manufacturing process that should be corrected as part of the transfer?
- Is tooling life adequate or near end of life?
- Has there been a shift in market demand that would make a specific region more advantageous?
- Are there new markets that could also be supported from the region under consideration?

Developing a broader perspective of the full range of improvements that could be achieved with the program transfer ensures a better evaluation of potential suppliers and their ability to support those requirements.

A Focus on Price Versus Total Cost

A contract manufacturing relationship includes both measurable and hidden costs. The manufacturer with the lowest price may lack the infrastructure necessary or experience to support a smooth transition. An effective analytical process looks at the total cost equation. Factors to evaluate include:

- Does the contractor have an experienced team with a proven transfer process?
- Can the contractor help us properly document our process (if the program has never been outsourced)?
- How much time will our team likely have to spend at this contractor's site managing the transfer?

- Can the contractor provide references from customers who have successfully transferred programs of similar size and complexity?
- Does the contractor have technical support in our region and the ability to schedule calls convenient to our time zone?
- Will the contractor help identify opportunities to reduce cost or improvement opportunities to the current process?
- Does the contractor have the expertise to properly maintain and repair tooling?
- Does the contractor have the expertise to re-align the supply chain?
- Can the contractor develop a strategy to reduce logistics costs through its partnerships in the region?
- Does the contractor have the regulatory expertise and credentials to support end market requirements?
- Does the contractor have a strong validation/qualification process?
- Can the contractor tap relationships to help us enter new markets?
- Does the contractor have a process for supporting cost reduction or product improvements over time?
- Can the contractor also support our new product development requirements?

Poor Understanding of Available Supplier Capabilities in the Preferred Transfer Region

Contract manufacturing is like any other industry. There are outstanding suppliers with a broad range of support and there are marginal suppliers who require significant oversight. One of the mistakes many companies make is assuming that a shift to a lower cost region automatically translates to a shift to a lower caliber supplier. The reality is that is a tradeoff that does not need to be made. Selecting a supplier with world-class processes in a lower cost region not only taps the lower costs of doing business in that region, but also reduces transfer cost and time.

For example, Forefront Medical uses a regional hub strategy that combines the best of Singapore's business advantages and skilled technical workforce while tapping China's lower labor cost and logistics advantages. In addition to being globally headquartered in Singapore, this location also includes their Engineering Design Center, micro molding, specialty catheters, rapid prototyping, product development and tooling fabrication for complex molds. Its two manufacturing facilities are located in China. The facility in Xiamen, PRC is primarily focused on production for export to other regions. The facility in Jiangsu, PRC facilitates and supports customers requiring a source of domestic production for the China market as well as for export, with an economic proximity to their R&D centers in Shanghai. Its U.S. Technical Center provides support in a convenient time zone to its U.S. customer base.

The result is a responsive supplier who supports the full product lifecycle from design through commercialization, plus helps its customers continue to improve and cost reduce their products as they mature.

Lack of a Robust Transfer Plan

The quality of the transfer plan typically determines whether or not a 'lift and shift' transfer achieves its desired goals. World-class contractors typically have a standardized transfer process that can be customized for each new project and an audit of this "standard" transfer process is one way to determine whether or not the contractor has the needed expertise and infrastructure for a seamless

transfer. And, while a good transfer plan can be customer developed and driven; that process typically carries more hidden cost than selecting a contractor with a proven transfer process.

Forefront Medical routinely adds value in its 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 was assigned to manage the transfer. Forefront's 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, Forefront Medical's engineering team made recommendations for enhanced product design and quality.

Unanticipated Regulatory Issues

Missed timelines due to a failed product qualification or facility audit, or a product recall, typically eliminate any near-term program transfer cost savings. Conversely, selecting a supplier with significant regulatory expertise can reduce both product qualification time and cost. There is even larger savings if that supplier's team can support the compliance issues associated with entry into new markets. As a result, this is an area to carefully evaluate in terms of both current and longer term program requirements.

A key part of Forefront Medical's partnership equation with its customers is its robust approach to ensuring superior quality and compliance with relevant regulatory processes. The foundation of the Company's World Class Manufacturing philosophy is to eliminate hidden costs before they occur.

There is strong focus on providing expertise on the global regulatory standards which customers' products must meet, since that is integral to rapid program transfers and long-term quality compliance in customer end markets. There is 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 of Forefront Medical's facilities are registered to ISO 9001:2008 and ISO: 13485:2003. The focus on third-party quality certifications does not stop there. 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.

Forefront Medical's facilities are FDA and Japan registered as foreign contract manufacturers. The Jiangsu, PRC facility currently holds a FDA Establishment Registration and Class II Product Registered (510k), as well as China FDA (CFDA). The focus on supplier quality includes both Forefront Medical's stringent supplier selection process plus the regulatory materials qualification process related to each product. Suppliers are required to undergo a monthly assessment of quality and delivery performance. There is also a rigorous incoming inspection process to ensure that every batch/lot meets acceptable quality levels.

Conclusion

A "lift and shift" program transfer can help reduce costs and grow market share. Selecting a contractor with a proven transfer process, regulatory expertise and the ability to provide strong engineering support over the life of program, helps ensure those goals are achieved.

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.

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