Outsourcing, Offshoring and the Partnership Equation

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Introduction

Outsourcing production of medical disposable devices and systems can be a complex process. Sourcing teams are faced with challenging questions. How can the dual requirements of superior quality and continuing cost reduction over time best be satisfied? Is the chosen contract manufacturer as concerned about regulatory requirements as my company? If I source offshore will our company's intellectual property (IP) be adequately protected? If tooling costs drive single-sourcing, how can I ensure the supplier will work on the cost reduction we need over time? Will our product development team be able to communicate with an offshore supplier's team? How much time will my team need to spend at an offshore contract manufacturer to get a project started?

The answer to those questions can vary widely by supplier. Forefront Medical Technology, a specialty contract manufacturer with a focus in disposable diagnostic, drug infusion and medical device systems, sees its mission as serving as an extension of its customers' product development teams. The Company focuses on driving cost out of products through a combination of efficient design and manufacturing processes plus robust project management processes. Additionally, vertically integrated prototyping and tooling fabrication capabilities, strategic use of lower cost labor markets and optimized logistics further eliminate non-value added cost.

The Singapore Advantage

Forefront Medical Technology is headquartered in Singapore, a regional hub for medical technology. According the Singapore Economic Development Board (EDB), the city-state is home to over 30 medical technology companies and the 10 largest medical technology companies have established regional headquarters there. Global leaders that have set up manufacturing, R&D centers and headquarter functions in Singapore include 3M, AB SCIEX, Baxter International, Becton Dickinson, BIOTRONIK, Hoya Surgical Optics, Life Technologies, Medtronic and Siemens Medical Instruments.

EDB statistics show a growing medical technology industry which almost tripled its manufacturing output from S$1.5 billion in the year 2000 to about S$4.3 billion in the year 2011. Over the same period, the segment's manpower base more than doubled from about 4,000 to 9,000. By the year 2015, EDB indicates that the medical technology sector targets to achieve S$5 billion in manufacturing output. What has driven that growth? Singapore has created an exceptionally business friendly environment, with government investment ensuring a strong technical infrastructure is maintained to support R&D, innovation and a supply base with the capabilities needed to support evolving industry technical requirements.

English is the official language of business and Singapore's legal system is based on English Common Law. The IMD World Competitiveness Report 2011 ranks Singapore the best place in Asia and 7th in the world for IP rights protection. The World Economic Forum's Global Competitiveness Report 2011-2012 ranks the city-state as having the best IP protection in Asia, and the second best in the world. Headquartering in Singapore has enabled Forefront Medical Technology to tap the knowledge base of one of the strongest medical regional hubs in Asia and work in an ethical business and legal environment that is transparent and compatible with customer preferences.

Maintaining Cost Competitiveness Via a Regional Approach

Forefront Medical Technology 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, the Company maintains engineering and tooling fabrication capabilities for prototypes, less complex molds and Liquid Silicone Rubber molds there. 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 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.

Forefront Medical Technology's initial facility within China was established in the Xiamen Export Processing Zone. Xiamen was one of the first four special economic zones (AEPZ) in China and one of the few municipalities enjoying independent status in state economic planning. Xiamen is located on the southeastern coast of China, to the west of Taiwan Strait. This location has made it one of the most important ports in China for international trade and cross-Straits trade.

Changzhou was selected as the site of Forefront Medical Technology's second facility, because it provides both logistical and tactical advantages. The facility is located in the Jiangsu Wujin Economic Zone, where there is a designated medical technology park, known as the West Taihua Lake International Medical Industrial Park, which is in close proximity to medical clusters in Shanghai and Suzhou. Mark Samlal, Forefront Medical's Chief Executive Officer serves a consultant to the park on medical device outsourcing considerations.

There is a globally renowned sterilizer in Suzhou and a China FDA office in the park. The park is located within 25 kilometers of local air and seaports, plus near the Yanjiang highway, which is the one of the main routes between Nanjing and Shanghai. Changzhou University Town is also near the park and features six schools that support the region's vocational training needs. Additionally, Changzhou is located in one of China's 'green' special economic zones. Companies in this zone are subject to more stringent regulation in terms of environmental regulations, and worker health and safety practices.

To provide customers with a responsive, cost competitive path to product commercialization, a flexible research and development (R&D) structure was designed that leverages existing engineering infrastructure in Singapore while localizing some tooling fabrication and maintenance functions at each of the China facilities. The Changzhou facility has a full scale commercial tool room with integrated support from the Singapore team. This provides the resources necessary to maintain tooling on-site, while tapping the resources of the Singapore engineering staff for new tool design. Actual tooling fabrication may be done in Singapore, in China or at qualified third-party suppliers depending on complexity of the tool and project requirements.

The Chinese engineering teams utilize the same design and mold flow analysis software found in Singapore for robust collaboration during the design and development phase. Forefront Medical Technology also operates a Technology Center in the U.S. fully linked to its engineering teams in Singapore and China, to provide an engineering interface in a time zone more convenient to its U.S. customer base. The Xiamen and Changzhou teams can handle product prototyping, the scale up of molds and tools, pilot runs, validations and product lifecycle management activities, accessing Singapore team resources as needed.

This strategy eliminates four potential sources of hidden costs. First, leveraging the Singapore team's expertise and resources enables the manufacturing facilities to pull specialized resources as needed from a centralized product development organization. Second, the U.S. Tech Center helps minimize customer product development team overtime and/or travel requirements. Third, the on-site tool room facilitates regular preventative maintenance which translates to less unscheduled downtime and higher product quality. Finally, an in-house facility also significantly shortens the amount of downtime for tool repair, compared to the time typically required by third-party tooling repair facilities, plus eliminates the transport costs associated with using a third-party firm.

Systems to Ensure Superior Quality

Poor quality can be a key driver of significant hidden cost in highly regulated industries. Time to commercialization is slowed when a contract manufacturer is unfamiliar with regulatory processes. A key part of Forefront Medical Technology's partnership equation 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.

All facilities, including Changzhou, 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.

All facilities are FDA and Japan registered as foreign contract manufacturers. The Jiangsu facility currently holds a FDA Establishment Registration and Class 2 Product Registered (510k), as well as China FDA (CFDA). The focus on supplier quality includes both Forefront Medical Technology'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.

Finally, there is strong focus on providing expertise on the global regulatory standards which customers' products must meet, since that is integral to rapid product development cycles 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.

Developing a True Partnership

At Forefront Medical Technology, the goal is to work with each to customer to manufacture market competitive products that meet customer goals over the entire product lifecycle. Speed is part of that equation. As an example, Forefront Medical Technology's product development team has a track record of taking 4-5 months off of product development cycles due to its robust design process and database of previously qualified materials suppliers.

Additionally, the Company's vertically integrated tool fabrication capability typically shortens product development cycles by another 2-3 months. Robust processes are also a key part of the equation. Product development, production qualification and production transfer processes are well defined with clearly identified points of customer review and approval. Customer teams can focus on a collaborative process vs. having to define and drive the process.

A focus on continuous improvement is another element of the equation. Because of the customized tooling and processes associated with its products, Forefront Medical Technology is often sole-sourced on the products it manufactures for the life of the product. The continuous improvement value-added process is part of the Company's efforts 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. The end result of a good sourcing partnership is simplification of an otherwise complex process. With Forefront Medical Technology, customer sourcing teams share their objectives and Forefront Medical Technology's team develops a high quality, cost effective solution that can be adjusted over time should requirements change.

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, 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.

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