FOREFRONT *Outsourcing Best Practices Series*

Issue 5

Key Considerations in Choosing a Product Development Partner

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Introduction

Outsourcing product development can provide a competitive edge in terms of expanding engineering resources, accessing specialized expertise or reducing time and/or overall cost. However, product development partners can vary widely in terms of the value provided. Additionally, while offshore product development firms can provide a cost advantage; careful consideration should be given to the quality of their processes and ability to work well multi-nationally.

Forefront Medical, a specialty contract manufacturer with a focus in disposable diagnostic, drug delivery and medical device systems has found that the best partnerships evolve when companies analyze potential working relationships and competencies in addition to price, when selecting a product development partner. This paper reviews eight areas to evaluate in that selection process:

- Ability to work well with your team
- Engineering expertise
- Materials expertise
- Defined product development process
- Intellectual property protection
- Manufacturability expertise
- Ability to align with cost goals
- Ability to meet quality assurance standards.

Ability to Work Well with Your Team

Product development is a people-driven process. Working relationships among teams can have a significant impact on the cost and time of a product development effort. In a strong relationship offshore time differences can become an asset because the end of the customer's day is the beginning of the work day for the contract engineering team. In that type of cycle, feedback at the end of the customer's day gets addressed by the time he returns to work the next day. Conversely, when distance or cultural differences create communication issues, the time lag becomes a liability and any cost savings can quickly disappear. In evaluating potential suppliers, analyze whether the supplier's team has fluency in your team's primary language, a track record of working in your part of the world and any support infrastructure in your team's time zone. A product development team that requires close management and significant face time can quickly eliminate any cost advantages, when travel cost is added up.

While Forefront Medical's engineering team is located in Singapore and China, it also operates a U.S. Technical Center to provide both the advantages of offshore pricing and localized support. Standardized design software platforms are used across the Company to ensure seamless communication during the design process.

Engineering Expertise
One of the challenges most internal product development teams face is being under-resourced for the workload required. Use of outside product development teams can fill resource gaps, plus provide access to a broader range of engineering expertise at a fraction of the cost of maintaining that breadth of capabilities in-house. That said, product development teams should be evaluated in terms of the skills they bring to supplement the internal team. The best partnerships are built when the device manufacturer analyzes the skills sets required for the project and then evaluates contract product development teams based on their ability to provide those skills.

Materials Expertise
One of the challenges of the highly regulated medical industry is that materials testing and approval can take 4-5 months. If the selected material fails testing, the 4-5 month testing and approval cycle starts over. This adds both time and risk to the design cycle. Working with a product development team that maintains a database of approved materials can eliminate that extra time and risk.

Forefront Medical maintains a database of approved materials which includes a full range of medical-grade polymers. While the best material will vary depending on application, cost considerations and desired functionality, Forefront Medical's team is often able to recommend pre-approved materials choices to reduce product development time.

Defined Product Development Process
Well-structured contract product development teams are in the business of designing product as quickly and efficiently as possible. Most have a well-defined product development process. This provides three key advantages. First, it provides a great tool for evaluating potential contract design team's understanding of the requirements upfront. Second, it makes it easier to understand key milestones and the likely pace of the process. Finally, it helps identify and eliminate potential bottlenecks and/or resource gaps.

Forefront Medical's team uses a standardized process in which customer requirements are assessed and a Design Development Plan (DDP) is created. A customer specification is then developed and market inputs are collected. Once the customer specification is approved, 3D CAD models are developed and analyzed. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began. Forefront's team also utilizes a gated design process to enable tooling development to begin as early in the design process as possible. This focus on a highly structured process cuts time and reduces tooling iterations.

Intellectual Property Protection
Intellectual property (IP) protection can be a point of concern for two reasons. First, one of the most common issues related to IP, when third-party product development teams are used, is misunderstandings about who owns key components related to the design. For example, some companies quote low or no tooling cost, but retain rights to the tooling and ownership of the design of

the part made by the tools. In any design agreement there should be clear understanding of who owns the tools and whether or not any components proprietary to the design team are used.

The other IP protection concern relates to product designs which are copied by offshore competition. When selecting a product development partner, look carefully at their internal checks and balances to prevent IP theft. Product development firms and contract manufacturers are highly dependent on maintaining good reputation and, as a result, typically don't engage in IP theft. When IP theft occurs, it is often done by an employee at a lower level supplier. It is not unusual for companies working in regions where IP theft has occurred to limit the amount of information shared with their suppliers for that reason. Look for product development partners who can discuss what they do to protect their customers' designs and proprietary information.

Forefront Medical is headquartered in Singapore. 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 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.

Manufacturability Expertise

The most brilliant product design is destined for quality issues and cost overruns if it isn't manufacturable. One of the benefits of working with a product development firm, that is part of a contract manufacturer, is normally the strong linkage between design engineering and manufacturing engineering teams. This helps reduce design iterations and eliminate defect opportunities.

The earlier manufacturability issues are analyzed in tooling development, the less expensive the tooling design modifications will be. Forefront has taken a vertically integrated approach to tooling fabrication and use of its in-house resources often cuts 2-3 months off of product development time. The tooling design process includes a design for manufacturability (DFM) phase, followed by development of the mold specification. Mold-flow analysis tools are used to ensure efficient molding with minimal scrap and minimization of secondary finishing processes. Computer analysis minimizes design iterations on tooling. Tooling iterations are a key performance indicator (KPI) for Forefront Medical's engineering team. The KPI target is no more than 2-3 iterations per product development process.

Ability to Align with Cost Goals

Because of the degree of tooling and automation, medical disposable products are often sole-sourced for the life of the product. Having a product development team that is closely focused on achieving customer goals for both quality and cost helps create a framework for continued cost reduction over time. For example, tool complexity and the most cost effective choices for tooling material can vary depending on overall cost goals and the likely life of the product line.

Forefront takes this goal alignment process a step further with its continuous improvement value-added process which identifies 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 market share.

Ability to Meet Quality Assurance Standards

The medical industry's high degree of regulation makes design mistakes costly, in terms of both time and money. The design process is further complicated by the fact that different countries have different regulations. Product development partners' expertise in the quality requirements for your products' end markets should be closely evaluated. This is an area where a knowledgeable partner with established relationships with regulatory bodies can reduce time in product development and validation process.

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).

Conclusion

The better project requirements are understood and potential product development partners are analyzed, the more likely an optimum design team will be chosen. While price is always a factor, the costs associated with the wrong choice can quickly eliminate any savings. Consider potential design teams' track record with similar products, synergies with manufacturing, breadth of engineering expertise and ability to add value to the process.

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 6062 7177 (Asia).