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Contract Manufacturer Selection: Key Areas to Audit

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Achieving total lowest cost in outsourcing is rarely achieved by selecting the contract manufacturer with the lowest unit price. Instead, it often is the result of selecting the contract manufacturer with the best focus on eliminating non value-added cost through well-defined processes and efficient commercialization strategies. This latter type of contract manufacturer is often identified during the plant tour phase where audit teams can see how the contract manufacturer has managed programs of similar manufacturing technology, size and scope.

Areas where contract manufacturer efficiency or expertise improves outcomes include:

- Product development
- Product launch
- Manufacturing capabilities
- Logistics support
- Continuous improvement
- IP Protection.

In this whitepaper, Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, discusses these areas and suggests questions to ask in the audit process.

Product Development

Most contract manufacturers are experts in efficient manufacturing processes. When contract manufacturers have in-house product development expertise, that value is multiplied significantly, because the product development team typically interacts with the manufacturing team and has a better understanding of manufacturability issues than independent product development teams who are siloed from manufacturing operations.

Questions to ask in auditing product development capabilities include:

- What does the product development process entail?
- What type of interaction occurs among product development engineers and manufacturing engineers
- How is manufacturability ensured?
- How are customer requirements documented?
- Are cost improvement suggestions made or do designs simply follow a purely customer-defined scope of work?
- How is tooling efficiency ensured?
- Who owns the design?

In new product development, Forefront Medical's team uses a standardized process in which customer requirements are assessed and a Design Development Plan (DDP) is created. The DDP is followed by a

customer specification and collection of market inputs. This approach enables Forefront's team to rapidly assess customer requirements, present design and manufacturing options and move forward with a design that incorporates all customer requirements and utilizes the optimum manufacturing technology or technologies for those requirements. Variables such as the feel of a device in a surgeon's hand, the ease of keeping tubing arranged by a hospital bed and patient comfort are all considered as these choices are made.

On the custom parts side of the equation, once the customer specification is approved, 3D CAD models are developed and analyzed, helping to optimize tooling performance prior to fabrication. Design reviews which include functional analysis and risk evaluation are completed. After a customer's team approves the design, prototyping and verification began.

To help shorten product development cycles, Forefront Medical also 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, the product development team is often able to recommend pre-approved materials choices to reduce product development time. Using materials that have previously been tested and approved within the regulatory environments associated with the product can cut 4-5 months from a product development cycle.

Forefront also maintains a detailed library of injection parameters related to the best mix of injection pressure, temperature, speed and other variables based on materials used. With standard molds and resins, developing optimal injection parameters utilizing this library typically takes two hours when injection molding is part of the production strategy.

On the electromechanical side of the equation, Forefront's design team provides electronics design and PCB layout, as well as software development services. Mechanical and packaging design can also be supported. Prototyping and validation are also provided.

Design for manufacturability (DFM) recommendations are made to ensure minimal secondary processing. Tooling and assembly lines are optimized for efficiency. Prior to tooling fabrication, simulation software is used to ensure the tooling design will achieve the desired cost and quality targets.

As part of the new product introduction (NPI) effort, Forefront collaborates with its customers on identifying any needed suppliers; risk management; machine, tools and process validation; product bio-compatibility and stability validation; sterilization validation including sealing integrity; and packaging ship testing.

Forefront also 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. Forefront's 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.

This broad range of engineering disciplines and manufacturing capabilities combined with software modeling capability creates a multi-disciplinary team focused on reducing time to market by working smarter.

Customer design ownership is defined prior to project start.

Product Launch

Product Launch or new product introduction (NPI) is the point where manufacturing assumptions are validated through pre-production and/or qualification runs. It is also a point where learning curve issues become evident. This phase can represent a hidden cost in the outsourcing process if resolving learning curve issues require significant OEM team presence and interaction.

Questions to ask during the audit include:

- What does the product launch/NPI process entail?
- How are potential issues documented and communicated to ensure they are corrected rapidly?

Forefront's SafeLaunch™ process helps ensure a robust production validation process, verifying product and process stability in an organized manner through audits during the validation process.

Areas audited include:

- Material receiving and incoming inspection
- Material storage conditions and security
- Work order issuing
- Material issuing and accountability
- Set-up, line clearance and first article inspection
- Production record of good vs. scrap
- Production run with 100% inspection on critical points
- Work order closure to determine if actual quantity aligns with system quantity.

The output of this audit process is a gap analysis on commercial run readiness which leads to development of an action plan. Data collection is used to determine if critical defects are detected. Once all the gaps are closed and pre-defined critical customer and product requirements are met, the team exits SafeLaunch™ and begins normal production.

In developing each SafeLaunch™ Plan, Forefront's team and the customer's team collaborate to assess potential defect opportunities and define a list of requirements that help prevent defects from occurring. Forefront's team then develops a control plan with checks and balances to prevent defects from occurring where possible, plus inspects critical to quality (CTQ) elements to ensure only defect-free product leaves the factory.

Visual inspection of incoming material helps ensure material conformance. Environmental issues that could impact product quality such as storage temperature and relative humidity are also monitored. Products are visually inspected to ensure conformance to product specification following assembly and that required finished goods packed quantities meet customer requirements. When indicated in the control plan, samples are pulled from each production lot for packaging and sealing strength tests. Potential sources of contamination are identified, and measures are taken to ensure that work-in-process (WIP) and finished product will be handled, packed and stored in ways that prevent this contamination issue from occurring.

The SafeLaunch™ process also considers Device History Recordkeeping requirements and ensures that required inventory inspection and control, production process tracking, and quality data is recorded and stored per customer and appropriate regulatory requirements.

Manufacturing Capabilities

Some contract manufacturers have one core manufacturing competency and utilize a group of associated suppliers to fabricate the parts the contract manufacturer doesn't manufacture in-house. In those cases, the contract manufacturer tends to recommend the manufacturing technology most closely aligned with their internal manufacturing competency. Comparatively, a vertically integrated contract manufacturer can evaluate multiple manufacturing technology options, making design recommendations based on the optimum technology for the product's form, fit, function and cost requirements. This expertise to rapidly evaluate multiple technologies reduces both time and cost.

Simplicity in managing the manufacturing process is another element to consider. The more capabilities a contract manufacturer must outsource to suppliers, the greater the number of silos in the manufacturing process. Each of those silos has separate scheduling priorities, which may not align with the contract manufacturer's priorities. Each silo also adds additional markup to the total project cost. Conversely, a vertically-integrated contract manufacturer can drive priorities across its manufacturing operations. Forecasts and production scheduling are handled through common systems. Freight costs are minimized or eliminated depending on whether the work is done in a single facility or multiple facilities. Less inventory is required as internal production eliminates the transit inventory "pipeline" present when parts are sourced from remote suppliers. When tooling fabrication is included in the capabilities mix, as in Forefront's case, there can be significant reductions in tooling lead-time and simplified maintenance logistics which translates to decreased downtime when the tool can be serviced in-house.

In the case of simple products aligned predominantly with a single manufacturing process such as molding or extrusion, selecting a contract manufacturer with only that in-house process may have little downside. In cases where the product involves multiple manufacturing processes, selecting a vertically integrated contract manufacturer may be the better choice.

Questions to ask during audit include:

- How closely do the contract manufacturer's core manufacturing capabilities align with my project?
- Does the contract manufacturer have unique engineering or manufacturing capabilities that are relevant to my project?
- Have there been any recent supply chain disruptions with suppliers fabricating parts that are outside internal competencies?
- How rapidly can unplanned demand increases be supported?

Forefront Medical's capabilities include Selective Laser Sintering (SLS) and Multi-Jet Modeling (MJM) systems, injection and blow molding, extrusion, metal fabrication, electromechanical assembly, clean room assembly capabilities and packaging. Forefront's design team does have electronic engineering and software development competencies, but sources PCBAs from suppliers specializing in board-level assembly for better economies of scale.

Logistics Support

Logistics has become a much larger portion of the cost equation as capacity constraints and fuel costs have driven prices up significantly. A contract manufacturer's expertise and relationships in this area can help eliminate unnecessary cost.

Questions to ask include:

- Does your team have a process for evaluating optimum logistics strategy?
- What examples can you give of situations where logistics costs were reduced or at least kept at parity through a logistics strategy you've developed?

Forefront Medical's team has significant experience in supply chain realignment to reduce logistics costs. Its facility locations have been selected for their proximity to major shipping hubs and support infrastructure such as contract sterilizers. This increases the options it can consider when logistics constraints are impacting delivery times.

Continuous Improvement

While no contract manufacturer can completely eliminate the issues caused by supply/demand imbalance in global markets, it is possible to mitigate that impact by improving internal efficiencies in the manufacturing process.

Questions to ask include:

- What processes are in place to drive continuous improvement activities?
- How are personnel trained in issue identification and problem solving techniques?
- What examples can you provide of situations where continuous improvement activities improved quality or reduced cost?

Six Sigma Green Belt training is in place in all Forefront facilities, creating teams with enhanced problem solving skills to lead continuous improvement focus in each facility. The core tools used to drive this process include:

- 7S Workplace Organization
- Poka Yoke mistake proofing technique
- 8D systematic approach problem solving methodology
- Risk management & Process Failure Modes and Effects Analysis (PFMEA)
- Statistical process control.

The teams start by developing a project charter which defines the problem statement, clear business objectives and benefits drivers. A Gemba workshop is then conducted with participation from various functions to identify potential areas of improvement, together with a time study to pinpoint bottlenecks. In Lean philosophy, Gemba means the place where value is created, and the technique is derived from the Toyota Production System. A more commonly recognized corollary in the management world would be Tom Peters' concept of "management by walking around." The Green Belt teams learn from observing the process and talking with production operators about their perspectives. Following Gemba, a focused DMAIC (Define, Measure, Analyze, Improve, Control) methodology is used to initiate the improvement process.

A DMAIC spreadsheet is used to capture information in a concise form. The benefit of this approach is that each identified improvement opportunity is thoroughly analyzed and tested to ensure root causes are correctly identified and the magnitude of the improvement benefit of implementing the corrective action is thoroughly understood.

For example, the team utilized a DMAIC process to identify potential improvements in throughput and cost on a recent project. Demand spikes had driven a need to switch to air shipment. The team's goal was to implement improvements that lowered overall project cost and also improved throughput to the point where surges in demand could be accommodated within the regular sea shipment schedule.

The team plotted a scattergram over two axes focused on opportunity impact and the effort associated with corrective action. That activity identified four opportunities with some impact and marginal effort. There were another three opportunities that offered greater impact at slightly higher effort and three opportunities that offered similar impact at a much higher effort.

The team then created a current state process map that mapped the production process flow, personnel, cycle time and takt time. They modeled a re-layout of the line for continuous flow vs a work cell arrangement. They then focused their efforts on two steps in the process: packaging the product in a tray and final sealing operation. The workstations were rearranged to enable operators to work with components more efficiently in a smaller space by utilizing stackable, color-coded bins to store raw material. Small changes were made to housekeeping and cleaning tools to eliminate dust particles not already eliminated by cleanroom filtration and production attire, reducing the time operators needed to spend cleaning each product during the packaging stage. From a throughput standpoint, the best opportunity for improvement was redesigning the automated sealing machine's sealing plate to have six cavities on each side instead of four. They also worked with the equipment manufacturer to develop a process that utilized both sides of sealing plate, instead of just a single side. The specification for the outer tray was also reviewed with the customer to better identify which visual defects should signal a rejected product. Discussions were also held with the tray supplier to minimize the opportunity for handling or shipping related cosmetic defects.

The result was a 50 percent improvement in throughput and a reduction in the need for air shipments.

Lean Six Sigma provides well-trained teams with a focused process and core tools for evaluating and prioritizing improvement opportunities. Even the best planned projects can have room for improvement when production requirements increase significantly. In the current environment of increasing cost and imbalance between supply and demand, Lean Six Sigma provides Forefront Medical's team with the resources to help mitigate increasing costs while increasing throughput and process yield.

IP Protection

Manufacturing cost reduction is meaningless if intellectual property (IP) is lost in the process. When IP theft occurs, the problem is often related to suppliers or even employees of suppliers, rather than a contract manufacturer. Consequently, in auditing a contract manufacturer it is important to understand that company's practices in terms of supplier selection, evaluation and documentation control.

Questions to ask include:

- What criteria are used in identifying and selecting key suppliers?

- Are suppliers audited for IP protection processes and contractually required to protect sensitive information?
- What processes are in place to limit the proprietary design information shared with any one supplier?

Forefront's internal manufacturing capabilities limit the need for outside suppliers of precision engineered parts. That said, when custom parts suppliers are required, Forefront's supply chain management team either uses the customer's preferred suppliers or recommends a supplier that has been audited by their team. All suppliers work under signed non-disclosure agreements (NDAs) and are expected to protect any information that is shared. To further mitigate risk, suppliers are only provided with basic documentation on the need-to-know basis, to build the components they are contracted to provide. The full product documentation package is not shared. Consequently, no one supplier has enough information to replicate a customer's product.

The location of the contract manufacturer's headquarters company should also be a consideration. A contract is only as good as the legal system that governs it. In countries with complex legal systems or minimal protections against IP theft, enforcing the contractual provisions may be costly and time consuming. Additionally, the legal framework, language of business and government efficiency can have significant impact on the cost equation. Areas to evaluate include:

- Does the country have strong penalties related to IP theft?
- How does that country score in global reports focused on IP protection?
- Will your current legal team be able to adequately evaluate the contract or will you need to retain a firm doing business in that country?
- What language must contracts be written in to be enforceable in the contract manufacturer's country and what checks and balances are in place to ensure the translation adequately reflects agreed upon terms?
- What is the typical timeframe for resolving contractual disputes in that country?
- Is there any evidence of bias against foreign companies in legal decisions?

Forefront is headquartered in Singapore and has manufacturing capability in both Singapore and China. The World Bank's "Doing Business" survey ranks Singapore number two for ease of doing business in a survey that measures a variety of activities including trading across borders, enforcing contracts, obtaining credit and paying taxes. English is the official language of business and its legal system is based on English Common Law.

Taking the time to evaluate the way a contract manufacturer interacts with customer teams, ensures process repeatability, achieves cost reductions over time and assures unique project challenges are addressed. It also helps better analyze that contract manufacturer's ability to support project requirements. While a quote response provides a comparative datapoint on initial pricing, a more thorough exploration of the way each contract manufacturer does business can be a better gauge of which supplier represents the best choice.

About Forefront Medical Technology

Forefront Medical Technology is a global medical device contract manufacturer with six 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. Arrow Medical, Kington, Herefordshire, UK, is now a part of the Forefront global capability, specializing in wound care products. Regional Business Development offices are located in Farmington, CT USA and Shanghai, China, and 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, electromechanical 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.

Forefront Medical's integrated technical approach provides customers the total manufacturing solution and global supply chain. Our facilities are TUV ISO 13485:2016 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 http://forefrontmedical.com/ to learn more about our capabilities. For a confidential review of your project, please complete our enquiry form at: http://forefrontmedical.com/contact-us/, email us at: appl_dev@forefrontmedicaltechnology.com, or call +1 (860) 830-4637 (Europe and America's) / +86 21 6062 7177 (Asia).