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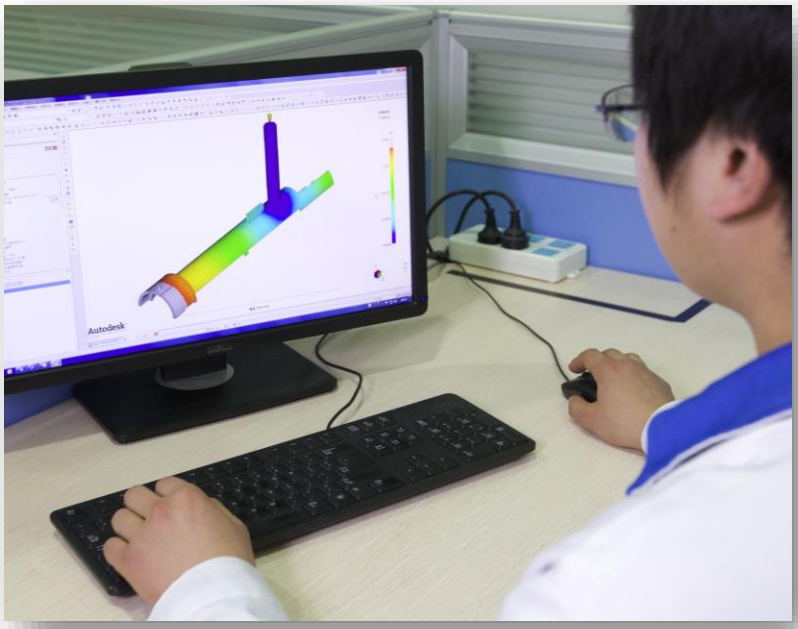

The Value of Established Processes in Ensuring Quality and Efficiency

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There are a range of business models in contract manufacturing. Some contract manufacturers have well-established manufacturing processes but depend on customers to define the process for sharing information, launching production or initiating continuous improvement efforts. Others have well-defined processes for these areas that can be adapted to customer requirements in addition to well-defined manufacturing processes. This latter business model is often more efficient because it streamlines the parts of the business relationship that can otherwise drive significant hidden cost.

Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, utilizes repeatable processes to ensure efficient product development, launch and continuous improvement. This whitepaper looks at these areas and discusses the benefits of this approach.

A Framework for Product Development

Product development efforts that involved outsourcing to a third-party often have two learning curves: the learning curve associated with teams developing an understanding of each other's working and communication styles, and the learning curve associated with translating desired product features and cost into a manufacturable design. When these activities are governed by a repeatable process, information flows more efficiently and questions are asked and answered proactively.

For example, 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.

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 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.

Industry-standard software is used for tool, hot runner and cooling system designs. Mold-flow software is used for mold-flow analysis and to support Design of Experiments (DoEs) to optimize the design and molding parameters when those parameters are not resident in Forefront's existing library. State-of-the-art software is utilized for molding process simulations to test assumptions prior to tool fabrication. Forefront 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.

This standardized approach enables tool designers to easily demonstrate the likely performance of the tool under review to the customer's team during the product development process.

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 comprehensive approach helps ensure that both the customer and contract manufacturer teams are considering all design options and eliminating defect opportunities and unnecessary cost drivers prior to product qualification.

A Repeatable Process for 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 manufacturing learning curve issues become evident. This phase can represent a hidden cost in the outsourcing process if resolving learning curve issues requires significant OEM team presence and interaction, particularly if the OEM team and contract manufacturer are in different parts of the world.

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.

Ensuring Continuous Improvement

It is common for OEMs with electronic products to change contract manufacturers multiple times over the life of a product because assembly line equipment is interchangeable. Conversely, products with customized tooling and assembly/packaging automation often stay with a single contract manufacturer. That said, changes in demand, market advantage or external costs often drive a need for improvement in the cost equation to balance the cost impact these variations drive. Selecting a contract manufacturer with a disciplined approach to improving production efficiency can help in that effort. When the quality framework also encourages team members to identify inefficiencies as they see them, waste is eliminated continuously.

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 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 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.

Repeatable processes of this nature help eliminate costly mistakes in product development, ensure design and process assumptions translate to manufacturable, superior quality products, and eliminate inefficiencies or unnecessary cost over time. They also foster a partnership among the OEM and contract

manufacturer teams that relieves unnecessary workload by leveraging supplier expertise and capabilities.

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).