Has Your Contract Manufacturer Laid the Groundwork for A Strong Quality Culture?

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The largest potential cost in medical device manufacturing isn't labor rate or cost of material. Instead, it is the cost of bad quality. Brand reputation depends on a medical device manufacturer's ability to put superior quality product where it is promised, when it is promised. Any failure that keeps that process from happening hurts a device manufacturer's reputation. When manufacturing is outsourced, reputation is also outsourced. As a result, the quality culture at a contract manufacturer is often a differentiating factor worthy of careful analysis. While third-party quality certifications validate that a quality management system that checks all the audit boxes exists, they don't do a good job of validating whether all levels of employees are fully engaged in ensuring product and service quality.

Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, believes that instilling a strong quality culture requires both rigorous processes and training programs that provide employees at all levels with the knowledge and tools to understand their contribution to ensuring product and service quality. This whitepaper looks at the building blocks for that level of engagement which include:

- A robust training program which gives employees the knowledge and tools to excel at their jobs
- Core quality disciplines that help eliminate defect opportunities
- Well-defined processes for product development and commercialization
- A Best Practice award program which rewards employees with continuous improvement suggestions.

Training

Creating a strong quality culture that can operate autonomously requires employees who are knowledgeable in the role their jobs play in delivering superior quality products and service. Forefront Medical's training program takes a three-part approach. Its on-the-job (OJT) training activities align with a certification program based on theorical and practical assessment. Its cross training program force multiplies its staff by enabling flexible deployment of cross-trained personnel based on production demand. Its re-training program provides reinforcement in areas where skills improvement is required.

Core Quality Disciplines

A key tenet of world class quality is a focus on not only preventing defects, but also on eliminating the conditions that create the opportunity for defects.

Forefront has begun Six Sigma green belt training in all its facilities, establishing teams with enhanced problem solving skills to lead a 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 use of 7S principles help eliminate defect opportunities by creating an orderly workplace. Originally developed in the Japanese automotive industry as 5S, this system become a foundation tool in Lean manufacturing and Total Quality Management philosophy for its ability to create an orderly workplace. The five elements are:

- Seiri (sort) focuses on sorting and cleaning up by defining which tools and materials are needed at the job site and throwing away anything that is not needed. This eliminates clutter and the inefficiency that occurs when that clutter makes needed items difficult to locate.
- Seiton (Set in order) focusing on straightening and arranging necessary information, tools and materials in the correct order for their designated areas. Visual tools are often utilized to maintain this order.
- Seison (Shine) recognizes that problems and inefficiencies are more visible when everything is neat and clean. Production personnel should look for minor defects while “sweeping clean.”
- Seiketsu – (Standardize) focuses on establishing a discipline of cleaning tools, equipment and the job immediately after use. Routine cleaning becomes a way of life.
- Shitsuke – (Sustain) is the most important discipline because employees must continue to maintain the 5S discipline continuously. This includes following all procedures and work instructions.

In Forefront’s model, the two additional elements are Safety and Security. The safety element focuses on a safe workplace environment compliant with safety regulations and standards applicable to that region. The security element focuses on logical and physical security, in promoting a culture and awareness of security within the organization. Regular security awareness training and an internal audit on workplace compliance coupled with phishing tests for employees are conducted by a recognized institute to keep security in check. Appropriate physical security elements and protocol are in place, ensuring that facility access is limited to only authorized personnel to help protect Forefront operations from terrorist activities and customer intellectual property theft.

The 8D methodology is predominately utilized as a framework for analyzing customer issues and defining the specific challenges to be solved. Originally deployed in the automotive industry, the 8D framework has grown in popularity as a tool in driving a highly standardized approach to continuous improvement throughout organizations. This type of standardized approach is beneficial in highly regulated industries where continuous improvement activities need to be balanced with customer requirements for process change notification.

Plan was added as discipline zero to the methodology after it was named, so technically there are nine disciplines. They are:

- Discipline 0: Plan
- Discipline 1: Form team

- Discipline 2: Define and Describe the Problem
- Discipline 3: Develop an Interim Containment Plan
- Discipline 4: Determine, Identify and Verify Root Causes and Escape Points
- Discipline 5: Choose and Verify Permanent Corrections for Problem/Non-Conformity
- Discipline 6: Implement and Validate Corrective Actions
- Discipline 7: Take Preventive Measures
- Discipline 8: Recognize the Team.

In Forefront's model, the PFMEA process is used as part of this activity to determine the extent of the issue and appropriately update documentation. All stakeholders including the subject matter expert are responsible for reviewing any proposed changes. Both technical and business issues are analyzed at this point.

The Poka Yoke technique is utilized in making a simple change/action to nonconformance issues by error proofing the process to prevent the nonconformance from reoccurring.

SPC is utilized to monitor critical processes and drive immediate reaction to variances to ensure it processes stay within control limits.

Product Development and Commercialization

Product development and project launch are two areas where miscommunication or learning curve issues can significantly impact product quality, cost and schedule. Forefront Medical's team has created two core processes designed to prevent that.

Forefront's product development process establishes the framework for collaboration and defines a detailed product specification, in which customer requirements are assessed and a Design Development Plan (DDP) is created. The customer specification reflects both customer and market inputs. This two-pronged approach of pulling information from the customer combined with studying the market helps ensure the initial specification adequately identifies all critical requirements. The customer specification provides a written document that aligns the teams in a shared vision.

Once the customer specification is approved, 3D CAD models are developed and analyzed to test assumptions related to the design and manufacturing process. Design reviews which include functional analysis and risk evaluation are completed. After the customer's team approves the design, prototyping and verification began. This phased process enables an evolutionary path to be taken should analysis or a review step indicate a change in approach would be beneficial.

Forefront's Safe Launch process helps ensure a robust production validation process, verifying product and process stability in an organized manner. 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 Safe Launch and begins normal production.

Best Practice Identification

Forefront's Best Practice award program encourages employees to apply the skills they've learned by suggesting improvements to existing processes. A Best Practice is defined as a modification of a methodology, equipment or activity that has demonstrated outstanding results and could be adapted to improve effectiveness, efficiency, ecology and/or innovativeness in another facility or situation.

The program gives a Gold, Silver and Bronze award every six months. Winners receive a monetary award and a pin. A panel of judges from Forefront's technical, operations, finance, quality and management teams evaluate the submissions. The evaluation criteria include:

- Creativity – the number of similar Best Practice submissions and originality of idea
- Cost Savings – manpower, material cost, etc.
- Customer Benefit – likely increase in customer satisfaction or appreciation
- Productivity – output or capacity increase
- Yield – rejection rate reduction.
- Safety/Security – safety or security enhancement.

Adopted Best Practices have included suggestions that reduce manpower, improve yield, improve safety, increase throughput and reduce cost.

In contract manufacturing, a strong quality culture translates to a knowledgeable team focused on meeting product quality and service commitments. It also leverages the expertise of the team members assembling product who often have the best understanding of critical process elements. That drives consistently superior quality and efficiency.

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 and Farmington, CT USA 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, 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.

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