On the FOREFRONT

A Quarterly Compilation of Outsourcing Best Practices and Case Studies

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Inside this issue:

Instilling a Quality Culture Requires Training and Tools

Forefront Medical provides rigorous training to all its production workers.

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 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.

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.

(Continued on page 2)

Forefront's Safe Launch Process Helps Ensure Quality

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

(Continued on page 2)

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Quality Culture

(Continued from page 1)

Its re-training program provides reinforcement in areas where skills improvement is required.

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

Engaged employees with the knowledge and tools to ensure quality in all the tasks they perform are critical to eliminating defect opportunities.

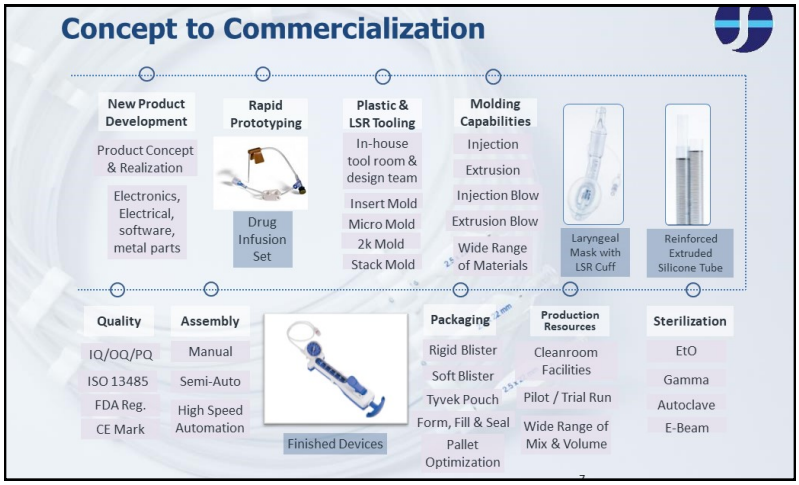
In contract manufacturing, a strong quality culture translates to a knowledgeable team focused on meeting product quality and service commitments. Providing extensive training in problem solving methodologies leverages the expertise of the team members assembling product who often have the best understanding of critical process elements and issues that contribute to defects. That drives consistently superior quality and efficiency.

Safe Launch

(Continued from page 1)

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.



Forefront's Safe Launch helps ensure the path from product development to commercialization has adequate checks and balances.

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 its Safe Launch and begins normal production.

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Forefront Medical Technology focuses exclusively on the medical device industry and thoroughly understands the needs of this market. As a specialty contract manufacturer with a focus in disposable diagnostic, drug infusion and medical device systems, Forefront Medical has extensive expertise with injection molding, extrusion, assembly and packaging of specialty medical disposable devices. In addition, Forefront Medical Technology's technical expertise extends into collaborative product design and development, rapid SLS prototyping, in-house tool making and isolated clean rooms for manufacturing, assembly and packaging. Capabilities also include sterilization and global logistics to provide one integrated source for the total supply chain. This world class supplier has the expertise to custom design a new product… or redesign the current one…from a conceptual drawing into a completely manufactured, packaged and sterilized product, ready for global shipment.

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Forefront's Best Practice Awards Reward Innovation

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:

Forefront Medical's Best Practice Awards encourages employees to look for ways to continuously improve processes.

- **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.