Safe Launch: A Process for Eliminating Defect Opportunities

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Outsourcing can bring many benefits: cost reduction, access to expertise not available in-house and reduction in working capital otherwise tied up in production resources. That said, when a medical device manufacturer outsources manufacturing, they are also outsourcing reputation. As a result, it is critical that the contract manufacturing partner take as diligent an approach to ensuring product quality as they would have the products been built in-house.

Extended team relationships can create communications issues. New product manufacturing always has a learning curve. These were some of the key issues the team at Forefront Medical Technology, a vertically-integrated specialty contract manufacturer with a focus in disposable diagnostic, drug delivery systems and medical device systems, considered when developing its Safe Launch Process.

The process builds on existing quality processes and best practices, auditing both business elements and critical-to-quality (CTQ) areas to ensure that both quality and quantities shipped align with customer requirements. This whitepaper looks at the typical issues that can occur within a new product startup and ways that the Safe Launch process is designed to catch and correct those issues.

Overview

Product development and project launch are two areas where miscommunication or learning curve issues can significantly impact product quality, cost and schedule. The Safe Launch process builds on Forefront's Design Development Plan (DDP).

Forefront's team works with customers who have new products in development or mature products requiring a shift to a lower cost labor market. When either product design assistance or redesign for cost reduction is involved, Forefront's design engineering group works under a DDP process designed to assess customer requirements and define a detailed product specification. 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. Tooling performance and throughput assumptions are tested via software modeling. Design reviews which include functional analysis and risk evaluation are completed. After the customer's team approves the design, prototyping and verification begin. This phased process enables an evolutionary path to be taken should analysis or a review step indicate a change in approach would be beneficial. Use of rapid prototyping technologies ensures that the customer team is able to see and handle a prototype as an additional check and balance in the process.

Forefront's Safe Launch 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 Safe Launch and begins normal production.

Eliminating Defects

In developing each Safe Launch 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 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.

Device History Recordkeeping

The Safe Launch 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.

A Focus on Creating a Strong Quality Culture

The DDP and the Safe Launch Processes reflect Forefront's commitment to instilling repeatable and organized processes throughout the product development and commercialization effort. Internal training is focused on giving Forefront's entire team the tools they need to prevent defects and identify issues that could create 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 focus on strong product development and project launch practices, plus an educated workforce with core tools to identify and mitigate inefficiency and defect opportunities, helps ensure superior quality from the earliest stage of any project.

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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