Design and Validation Strategy for Medical Device Product Transfer

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Abstract

The transfer of medical device products from development to manufacturing presents multifaceted challenges that demand meticulous planning and execution to ensure product quality, regulatory compliance, and cost-effectiveness. This article proposes an integrated approach leveraging principles of lean manufacturing and Six Sigma methodology to streamline the design and validation processes during product transfer. The application of lean manufacturing principles enables the identification and elimination of non-value-added activities, thus optimizing the transfer process for efficiency and resource utilization. Concurrently, Six Sigma methodology offers a structured framework for reducing variation and enhancing product quality through data-driven decision-making. This article outlines a comprehensive strategy encompassing key stages of product transfer, including design transfer planning, process validation, and risk management. Each stage is systematically analyzed and optimized to achieve seamless transition while meeting regulatory requirements and customer expectations.

Key Term − Design validation, Lean manufacturing, Product transfer, , Six Sigma.

Problem Statement

The transfer of medical device products between manufacturing facilities poses significant challenges when there are gaps in the design and validation strategy. Such gaps may manifest in inconsistencies in product specifications, manufacturing processes, or quality standards, leading to variations in product performance and regulatory compliance. Without a robust strategy integrating lean manufacturing and Six Sigma methodologies, these discrepancies can escalate, resulting in delays, increased costs, and compromised patient safety. Furthermore, the lack of alignment in design and validation approaches between the originating and receiving facilities exacerbates the problem, exacerbating communication breakdowns and hindering seamless knowledge transfer. These discrepancies may arise due to differences in organizational cultures, resource capabilities, or regulatory interpretations. Without a synchronized strategy, the transfer process becomes fragmented, impeding the achievement of key objectives such as efficiency improvements and regulatory compliance. Addressing these gaps requires a holistic approach that not only identifies and bridges the disparities but also establishes standardized procedures and metrics to ensure consistency and continuous improvement across manufacturing sites.

Methodology

Lean Six Sigma is a powerful methodology that combines the principles of Lean Manufacturing and Six Sigma to improve processes, reduce defects, and enhance efficiency. Here's an overview of the Lean Six Sigma methodology (see Figure 1).

Figure 1: DMAIC

Results and Discussion

Define Phase

During the design and validation strategy of a medical device transfer, process gaps were encountered during the initial development steps. Inadequate part measuring at the sending facility is a serious risk to product integrity and quality control. Operators may unintentionally pass defective components as acceptable when parts are not measured in accordance with Geometric Dimensioning and Tolerancing (GD&T) fundamentals. The dependability of quality inspections is compromised by this disregard for GD&T standards, which may permit defective components to pass through production or assembly processes undetected. Consequently, if faulty parts find their way into finished goods, this oversight may result in a rise in rework or scrap, a decrease in customer satisfaction, and a breach of safety standards (see Table 1).

Table 1
Problem Statement

Affected Process:	Medical Device Transfer
What is the problem? Why?	The sending facility does not measure the parts according to GD&T guidelines. The operator can pass bad parts as good parts by not measuring the parts properly.
What is the goal?	Measure the parts according to GD&T fundamentals
Staff:	Manufacturing Engineer, Operators, Programmers, Quality Engineer, Project Manager, Tool Engineer, and Engineering Manager

Measure Phase

Using the actual inspection SOP from the sending facility, 3 lots of 50 parts were selected, and 5 different operators remeasured them to see if any bad parts were accepted as good parts. (See Figures 1, Figure 2, Figure 3 and Figure 4).

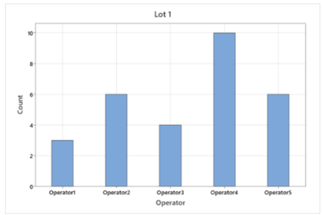


Figure 2
Bad Parts Identified from Lot 1

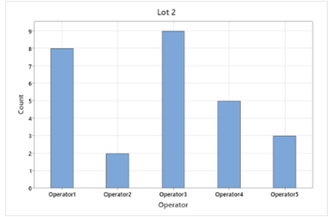


Figure 3
Bad Parts Identified from Lot 2

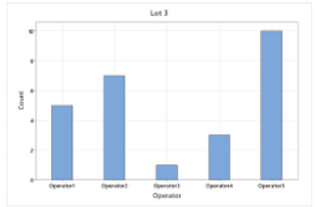
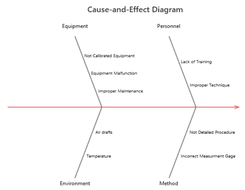


Figure 4
Bad parts identified from Lot 3

Results and Discussion

Analyze Phase

This phase aims to investigate how inadequate measurement practices allow operators to pass defective parts as acceptable ones. By analyzing the root causes and consequences of this problem, we can lay the groundwork for effective solutions that enhance measurement protocols and ensure quality standards are met. (See Figure 5).



Improve

Implementing effective solutions is critical for improving measurement accuracy and adherence to standards. Fostering a culture of continuous improvement and accountability within the organization can encourage adherence to standards and drive sustainable improvements in measurement practices. By systematically addressing root causes and implementing these solutions, organizations can optimize measurement accuracy, enhance product quality, and mitigate risks associated with non-compliance with GD&T guidelines. The graphs represent the improvement of bad parts identified after the implementation of several controls in the machining process. (See Figures 6, Figure 7 and Figure 8).

Figure 6
Bad Parts Identified from Lot 1

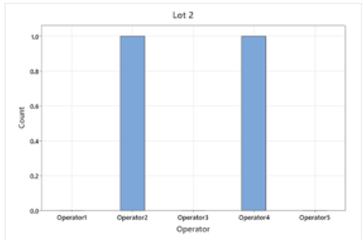


Figure 7
Bad Parts Identified from Lot 2

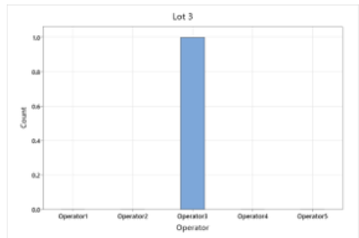


Figure 8
Bad Parts Identified from Lot 3

Results and Discussion

Control

The emphasis turns to preserving reliability and consistency. Regular audits will be performed to ensure compliance with SOPs and gage calibration schedules. Key performance indicators (KPIs) such as process capability indices and defect rates will be regularly tracked. Any deviations will be handled promptly using approved corrective action processes. Furthermore, continuing training programs will be implemented to reinforce best practices and keep operators informed of any procedure changes. By employing these control methods, the goal is to maintain the improvements that were obtained.

Conclusion

The root causes for the high variability and large number of defective parts that were dispatched as good ones were found throughout this investigation. Both manufacturing facilities implemented the results after sharing them with the sending facility. This ensures that every product shipped out from both facilities are being dimensionally inspected accurately in accordance with GD&T guidelines. DMAIC allowed for the identification of the root causes of the problem, improvement, and assurance that the two manufacturing plants were maintaining the improvements made.

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