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APPLYING LEAN AND SIX SIGMA IN THE MAINTENANCE OF MEDICAL IMAGING EQUIPMENT MANUFACTURING LINES

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Abstract
This study explores the strategic application of Lean and Six Sigma methodologies in the maintenance systems of medical imaging equipment manufacturing lines. Given the complexity, precision requirements, and stringent regulatory standards involved in producing devices such as MRI, CT, and ultrasound systems, effective maintenance is vital to ensuring consistent equipment performance, regulatory compliance, and product quality. Despite the proven benefits of Lean and Six Sigma in various industrial and healthcare sectors, their targeted application within the context of imaging equipment maintenance remains underexplored. To address this gap, the study conducted a systematic review of 42 peer-reviewed articles, selected and analyzed using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The findings demonstrate that Lean tools like 5S, Value Stream Mapping, and Total Productive Maintenance (TPM), when combined with Six Sigma techniques such as DMAIC, FMEA, and control charts, significantly enhance equipment uptime, reduce maintenance variability, and improve metrics such as Mean Time Between Failures (MTBF) and Overall Equipment Effectiveness (OEE). Furthermore, the study finds that these methodologies promote better documentation, risk-based maintenance planning, and stronger alignment with regulatory frameworks such as ISO 13485 and FDA 21 CFR Part 820. Enhanced cross-functional collaboration and operator engagement were also identified as key enablers of sustained improvement. However, the review also reveals challenges, including variability in implementation outcomes, a lack of sector-specific LSS models, and insufficient empirical benchmarking. As a result, the study recommends the development of customized Lean Six Sigma frameworks tailored to the specific demands of imaging equipment manufacturing. These frameworks should integrate digital maintenance intelligence, compliance-focused documentation, and cross-functional ownership to achieve long-term reliability and regulatory excellence. This review contributes to a deeper understanding of how Lean and Six Sigma can support high-performance, compliant, and efficient maintenance in medical imaging manufacturing.

Keywords
Lean, Six Sigma, Maintenance, Medical Imaging, Manufacturing

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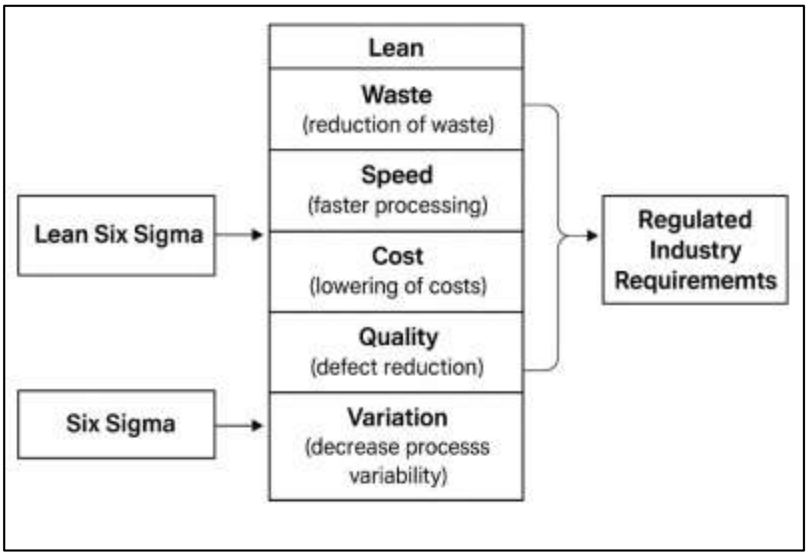
INTRODUCTION

Lean and Six Sigma are two of the most influential methodologies used to enhance operational performance across various industries, especially in manufacturing. Lean focuses on reducing waste (muda) and improving process efficiency, while Six Sigma emphasizes the reduction of process variability and the improvement of quality using data-driven tools (Chiarini & Kumar, 2021). When integrated, Lean Six Sigma becomes a holistic framework that addresses both speed and quality, making it highly applicable to environments requiring precision and consistency. In the context of industrial maintenance, particularly in manufacturing, the two methodologies help shift maintenance from a reactive to a proactive function, aiming to improve equipment uptime, reduce failures, and ensure stable production (Stankalla et al., 2018). Maintenance strategies under Lean Six Sigma often include tools such as Total Productive Maintenance (TPM), Root Cause Analysis (RCA), and Failure Mode and Effects Analysis (FMEA), which are aligned to prevent breakdowns and optimize asset performance. These tools support data collection and analysis to uncover the root causes of system inefficiencies, allowing organizations to create more reliable and cost-effective maintenance plans (Makwana & Patange, 2021). Moreover, the use of statistical process control (SPC) in Six Sigma allows manufacturers to monitor process stability and identify early warning signs of equipment degradation. This combined approach is particularly vital in regulated industries like medical device manufacturing, where equipment reliability directly impacts product safety and quality.Thus, Lean Six Sigma's application in maintenance transcends simple operational improvements. It fosters a culture of continuous improvement, where maintenance activities are integrated into the broader goals of productivity, quality, and compliance, especially critical in high-precision sectors like medical imaging equipment production (Panwar et al., 2018).

Figure 1: Lean Six Sigma Maintenance Framework



The manufacturing of medical imaging equipment such as MRI, CT, PET, and ultrasound machines is a globally significant industry due to its direct impact on healthcare diagnostics and treatment quality. These machines are critical for early disease detection and patient monitoring, making their production a high-stakes endeavor where quality and precision are paramount (Gupta et al., 2020). Given their complexity and the necessity for stringent compliance with regulatory standards like ISO 13485 and FDA 21 CFR Part 820, the maintenance of manufacturing lines becomes a mission-critical activity. Any disruption in production due to equipment failure not only causes financial losses but can lead to delays in patient care worldwide.In an international context, manufacturers often operate globally distributed production networks, relying on consistent equipment performance and harmonized processes to ensure standardization and efficiency (Kaswan & Rathi, 2020). Lean and Six Sigma methodologies serve as unifying frameworks that help multinational organizations maintain equipment reliability while meeting diverse market regulations and customer expectations. Techniques like 5S, visual controls, and statistical quality control promote operational transparency

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and error reduction across cultural and geographic boundaries (Lizarelli & Alliprandini, 2020). These practices are especially vital when operating in just-in-time environments with limited inventory buffers.Medical imaging manufacturers such as Siemens Healthineers, GE Healthcare, and Philips extensively implement Lean Six Sigma in their maintenance operations to ensure uninterrupted output and global quality uniformity. Hence, robust maintenance practices supported by Lean and Six Sigma are not only desirable but essential for ensuring the timely delivery of life-saving diagnostic equipment to healthcare systems worldwide (Rathi, Kaswan, et al., 2022).

Maintenance in high-precision manufacturing, especially in the medical imaging equipment sector, is fundamentally strategic. These production lines involve technologically complex processes, including fine-tuned electromechanical systems, embedded sensors, and high-frequency components that require tight tolerances and meticulous quality control (Hill et al., 2018). Equipment failure or process drift, even within small margins, can lead to defective outputs, regulatory noncompliance, or field failures with serious clinical implications. As such, maintenance transcends its traditional reactive role and evolves into a critical function that sustains product integrity, regulatory compliance, and operational throughput (Möldner et al., 2020). In this environment, Lean and Six Sigma principles provide a structured, proactive framework for managing the health and reliability of equipment assets. Lean tools such as Total Productive Maintenance (TPM), autonomous maintenance, and kaizen engage production operators in daily equipment care and minor repairs, creating a shared responsibility for asset performance (Bai et al., 2019). Meanwhile, Six Sigma methods including Failure Mode and Effects Analysis (FMEA), control charts, and Root Cause Analysis (RCA) facilitate data-driven identification of chronic maintenance problems and optimization of preventive strategies.Empirical studies have demonstrated that firms adopting these methodologies in their maintenance systems experience improvements in Mean Time Between Failures (MTBF), reductions in Mean Time to Repair (MTTR), and more predictable maintenance scheduling. These metrics directly influence production continuity and overall equipment effectiveness (OEE), making Lean Six Sigma critical to maintaining high operational standards in medical equipment production (Tissir et al., 2023). Therefore, maintenance in this sector is not a background operation—it is central to quality assurance and the reliable delivery of life-critical devices.

The integration of Lean and Six Sigma into maintenance systems signifies a shift from corrective and preventive models to predictive and reliability-centered maintenance frameworks. In traditional maintenance, breakdowns are treated as isolated incidents, often resolved without systemic improvements. However, Lean Six Sigma promotes the continuous identification and elimination of root causes, using tools such as the DMAIC (Define, Measure, Analyze, Improve, Control) cycle to systematically improve asset reliability and process stability (Sreedharan et al., 2018). Within this structure, data collection becomes essential, enabling maintenance teams to monitor patterns of failure and apply corrective action proactively.Lean techniques such as 5S, value stream mapping, and visual management aid in organizing maintenance workspaces, improving communication, and eliminating inefficiencies. When combined with Six Sigma's statistical rigor—using tools like control charts, Pareto analysis, and regression modeling—organizations can make evidence-based decisions that enhance equipment performance and reduce unplanned downtime (Alarcón et al., 2023). This is especially critical in environments that demand zero defects and minimal process variation, as is typical in medical imaging equipment manufacturing.Furthermore, Lean Six Sigma integration enables the deployment of Condition-Based Maintenance (CBM) and Predictive Maintenance (PdM) by leveraging process data to identify early signs of degradation or abnormal behavior (Byrne et al., 2021). These approaches enhance the responsiveness of maintenance systems while minimizing disruptions to production. Organizations that apply Lean Six Sigma principles also benefit from cross-functional collaboration, where maintenance engineers, quality managers, and production staff jointly work to sustain continuous improvement initiatives (Garza-Reyes et al., 2018). This integration, therefore, builds a culture of ownership and shared accountability essential for sustaining high-reliability manufacturing systems.

The application of Lean Six Sigma in maintenance systems delivers significant operational benefits that extend across productivity, quality, and cost dimensions. One of the most immediate advantages is the reduction in equipment downtime through improved maintenance scheduling and faster root cause identification (Yadav et al., 2018). When downtime is minimized, production lines operate more consistently, and throughput increases, enabling firms to meet customer demand without compromising quality. This is especially relevant in medical imaging equipment

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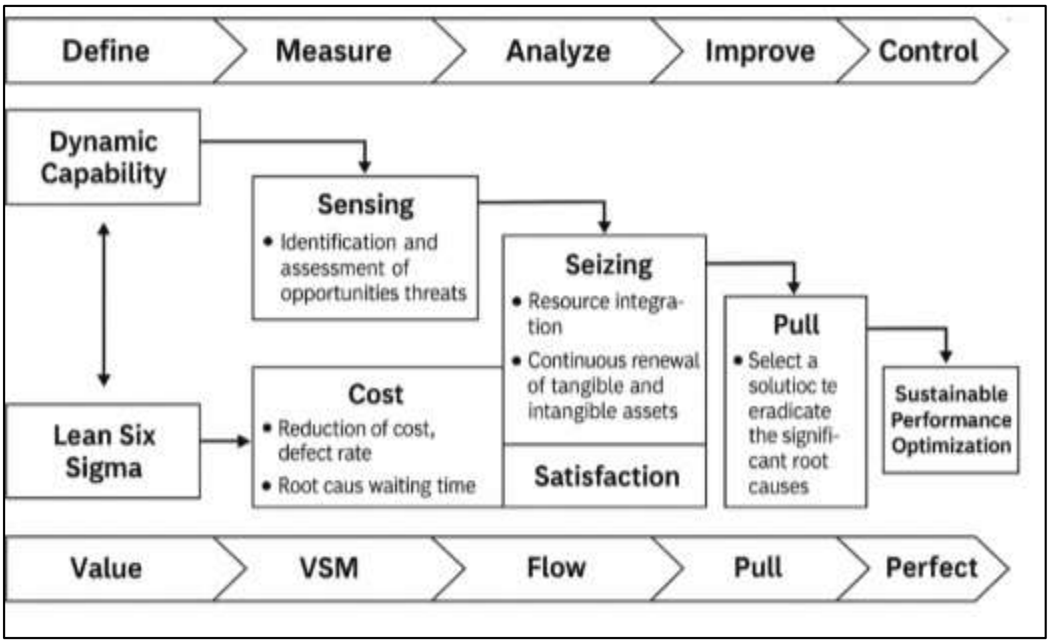
manufacturing, where delays can affect both regulatory timelines and the availability of critical healthcare technologies.Another key benefit is enhanced asset utilization. By employing statistical tools from Six Sigma such as process capability analysis (Cp, Cpk) and control charts, maintenance teams can track equipment stability and performance trends over time (Cudney et al., 2020). These insights inform preventive actions and allow for precise scheduling of maintenance tasks, thereby avoiding unnecessary interventions and reducing maintenance costs. Similarly, Lean practices such as standard work instructions and quick changeover techniques (SMED) streamline routine maintenance tasks and reduce variability in maintenance execution. Lean Six Sigma also contributes to better spare parts inventory management by analyzing consumption patterns and identifying non-value-added stockholding, which reduces costs and ensures part availability when truly needed (Sony et al., 2020). These cost savings contribute to leaner operations and enhanced profitability, while also reinforcing regulatory compliance through documented, standardized maintenance protocols. Organizations applying these methodologies often report improvements in Overall Equipment Effectiveness (OEE), a composite metric measuring availability, performance, and quality—key indicators of manufacturing excellence (Mohan et al., 2022). Thus, Lean Six Sigma transforms maintenance into a strategic lever for competitive advantage.

Figure 2: Lean Six Sigma Optimization Model



Empirical evidence from various manufacturing sectors supports the successful integration of Lean and Six Sigma in maintenance systems, with numerous case studies documenting measurable improvements in equipment reliability and process efficiency. For instance, a study by Debnath et al. (2023) a precision manufacturing environment showed a 30% reduction in downtime and a 20% increase in Mean Time Between Failures (MTBF) after implementing TPM within a Lean Six Sigma framework. Similarly, research on healthcare device manufacturers found statistically significant improvements in yield and cycle time following DMAIC-based maintenance improvements. These results illustrate the practical value of combining Lean tools like 5S and value stream mapping with Six Sigma techniques such as control charts and FMEA.Global corporations in the medical device industry have also reported positive outcomes from such integration. GE Healthcare, for example, credits Lean Six Sigma with reducing warranty claims and improving product reliability through structured maintenance interventions. Philips and Siemens Healthineers have documented reductions in rework, faster equipment changeovers, and better compliance audit outcomes attributed to disciplined maintenance protocols aligned with Lean Six Sigma principles (Vashishth et al., 2019). These real-world applications reinforce the transferability of Lean Six Sigma beyond generic manufacturing to specialized, high-compliance sectors such as medical imaging equipment production.Moreover, academic analyses have demonstrated that Lean Six Sigma enhances workforce engagement and fosters a culture of ownership in maintenance departments. When maintenance teams are trained in structured problem-solving and statistical reasoning, they contribute more effectively to continuous improvement efforts, reinforcing organizational learning and resilience (Belhadi et al., 2020). Such empirical and industrial validation underlines the credibility of Lean Six Sigma as a foundation for robust, sustainable maintenance performance in the medical manufacturing context.

The medical imaging equipment manufacturing industry operates under strict regulatory regimes that demand high standards of product quality, safety, and documentation. Regulatory bodies such as the U.S. Food and Drug Administration (FDA), the International Organization for Standardization (ISO), and the European Medicines Agency (EMA) impose stringent controls that mandate traceability, repeatability, and validation of all processes, including maintenance activities. Lean Six Sigma aligns with these regulatory frameworks by formalizing maintenance operations through standard operating procedures (SOPs), quality metrics, and data-driven decision-making processes. The use of Six Sigma tools such as Statistical Process Control (SPC), process mapping, and cause-and-effect analysis enables organizations to demonstrate process stability and capability, which are often required in compliance audits and certification processes. Lean practices, particularly 5S, visual controls, and mistake-proofing (poka-yoke), further contribute to regulatory readiness by enhancing workplace organization, reducing human error, and standardizing maintenance routines. These features are vital in manufacturing environments where even minor deviations can compromise product integrity or delay regulatory approvals. For instance, poorly maintained equipment may lead to product non-conformities, increased rework, or even batch recalls—events that are costly and reputationally damaging (Tripathi et al., 2021).Moreover, Lean Six Sigma fosters a culture of continuous compliance by embedding quality thinking into the fabric of maintenance processes. With structured training and cross-functional collaboration, maintenance personnel become active participants in quality assurance efforts, enhancing responsiveness to audits and inspections. As the manufacturing of medical imaging devices becomes more technologically advanced and globally distributed, aligning maintenance practices with Lean Six Sigma principles ensures both operational excellence and sustained regulatory conformance, reinforcing trust in the medical devices produced.

LITERATURE REVIEW

The integration of Lean and Six Sigma methodologies into the maintenance functions of high-precision manufacturing industries has gained considerable scholarly and industrial attention. In medical imaging equipment manufacturing—where production systems are defined by their complexity, precision, and strict regulatory oversight—maintenance plays a vital role in ensuring equipment uptime, product quality, and compliance. The literature surrounding this intersection spans several disciplines, including operations management, quality engineering, maintenance science, and medical device compliance. A review of existing research reveals a growing emphasis on proactive, data-driven maintenance strategies such as Total Productive Maintenance (TPM), Condition-Based Maintenance (CBM), and Predictive Maintenance (PdM), all of which are enhanced by Lean and Six Sigma frameworks. Numerous empirical studies and case-based investigations have validated the operational benefits of Lean Six Sigma in reducing equipment failures, standardizing procedures, and improving performance metrics such as Mean Time Between Failures (MTBF), Overall Equipment Effectiveness (OEE), and process capability indices (Cp, Cpk) (Belhadi et al., 2023). However, the literature also underscores the necessity of aligning these methodologies with industry-specific challenges such as cleanroom protocols, traceability demands, and multi-layered regulatory compliance systems like ISO 13485 and FDA 21 CFR Part 820. Furthermore, while much of the early work focused on discrete manufacturing or general medical device production, few studies provide detailed frameworks for their application in the unique context of imaging equipment—where downtime directly impacts healthcare delivery. This literature review synthesizes previous research by organizing the discussion into targeted thematic areas: conceptual foundations of Lean and Six Sigma in maintenance; their deployment in the medical device industry; critical success factors; integration frameworks; empirical outcomes; and research gaps (Ghaithan et al., 2023). The structure is designed to offer both breadth and depth, culminating in a focused understanding of how Lean Six Sigma can be systematically applied to optimize maintenance in medical imaging equipment manufacturing lines (Shahin et al., 2023).

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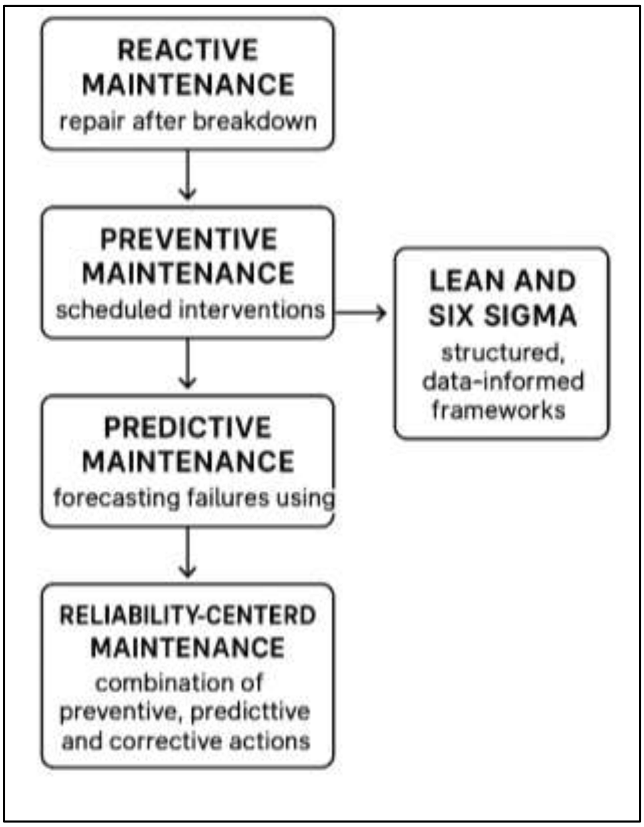
Lean and Six Sigma in Maintenance Operations

The evolution of maintenance strategies reflects a shift from reactive approaches toward structured, data-informed frameworks aimed at ensuring asset reliability and optimizing operational performance. Early industrial maintenance predominantly followed a reactive or "run-to-failure" model, where equipment was repaired only after breakdown, often resulting in unplanned downtime, safety risks, and increased operational costs (Gijo et al., 2018). As production systems grew more complex, preventive maintenance emerged, involving scheduled interventions to reduce the likelihood of failure. Preventive strategies were found to extend equipment life and stabilize performance but also risked over-maintenance and resource inefficiency. To address these limitations, predictive maintenance approaches were introduced, leveraging sensor technologies, vibration analysis, and condition monitoring to forecast failures based on real-time operational data.Reliability-Centered Maintenance (RCM) further advanced this trajectory by emphasizing the criticality and failure modes of assets to determine the most appropriate maintenance strategy, combining preventive, predictive, and corrective actions as needed. In high-precision industries like medical imaging equipment manufacturing, this evolution is critical because equipment failure can directly compromise product quality and regulatory compliance. The literature supports the strategic alignment of maintenance with operational and quality objectives, especially under frameworks like Lean and Six Sigma that formalize continuous improvement (Yang et al., 2022). Furthermore, data-driven maintenance planning is bolstered by digital technologies such as Computerized Maintenance Management Systems (CMMS), which centralize work orders, maintenance histories, and performance analytics. As maintenance transforms into a strategic function, it aligns with broader manufacturing goals such as reduced waste, increased equipment uptime, and sustainable asset management (Thomas et al., 2021). This strategic shift provides a strong foundation for integrating Lean and Six Sigma into maintenance practices, particularly in sectors requiring operational precision and regulatory rigor.

Figure 3: Maintenance Strategy Evolution Flow Diagram



Lean maintenance, derived from the broader Lean manufacturing philosophy, focuses on reducing non-value-added activities, standardizing operations, and empowering frontline workers to maintain equipment reliability. Central to this approach is the concept of Total Productive Maintenance (TPM), which promotes autonomous maintenance by equipment operators, with the goal of achieving zero breakdowns and fostering shared responsibility. TPM integrates multiple Lean tools—including 5S, kaizen, visual management, and standardized work—to maintain equipment in optimal condition while embedding a culture of continuous improvement. The 5S methodology—Sort, Set in order, Shine, Standardize, and Sustain—plays a foundational role by organizing maintenance areas, ensuring cleanliness, and eliminating unnecessary tools or materials, thereby reducing search time and promoting early detection of anomalies. Visual controls and standard operating procedures (SOPs) further support Lean maintenance by making abnormalities visible, facilitating quick responses, and promoting uniform task execution across shifts (Krishnamoorthi & Krishnamoorthi, 2018). Kaizen events, focused on incremental improvements, allow teams to collaboratively identify inefficiencies in maintenance workflows and implement process enhancements. These practices have proven effective in reducing Mean Time to Repair (MTTR), improving equipment availability, and enhancing workforce engagement. In the context of medical imaging equipment manufacturing, where uptime and precision are paramount, the structured application of Lean maintenance reduces human error and enhances the predictability of production processes (Ghansah & Lu, 2023).Empirical studies affirm that Lean maintenance contributes to higher Overall Equipment Effectiveness (OEE), with reductions in unplanned downtime and defect rates across various manufacturing settings. Furthermore, by empowering equipment operators through training and clear visual systems, Lean maintenance promotes decentralized problem-solving and faster issue resolution, critical in high-stakes production environments. This body of literature highlights Lean maintenance as a disciplined, systematic strategy for sustaining high equipment performance and aligning maintenance with enterprise-wide productivity goals.

Six Sigma offers a statistically rigorous framework for enhancing equipment performance by systematically identifying and eliminating sources of process variation and failure. Central to Six Sigma is the DMAIC methodology—Define, Measure, Analyze, Improve, Control—which guides structured problem-solving and root cause identification in maintenance and quality management (Sichinsambwe et al., 2023). In the maintenance context, DMAIC enables teams to define performance goals, measure equipment performance data, analyze failure modes, implement targeted improvements, and maintain long-term process stability. These steps are supported by statistical tools such as control charts, process capability indices (Cp, Cpk), hypothesis testing, and regression analysis, which allow maintenance engineers to move from intuition-driven decisions to data-based strategies. Another key methodology within Six Sigma is Failure Mode and Effects Analysis (FMEA), used to prioritize equipment failure risks based on severity, occurrence, and detection ratings. In medical imaging equipment manufacturing, where even minor failures can compromise regulatory compliance and patient safety, FMEA is vital for designing robust maintenance protocols and scheduling preventive interventions. Design of Experiments (DOE) is also employed to optimize maintenance variables such as lubrication intervals, part replacements, and calibration frequencies, reducing both cost and variability. Six Sigma's value lies in its capacity to integrate statistical quality control with continuous improvement, producing sustainable gains in equipment uptime and reliability. Studies across diverse industries have shown reductions in equipment failure rates by over 25% when Six Sigma methodologies are systematically applied. The emphasis on evidence-based analysis, predictive modeling, and control systems makes Six Sigma particularly effective in maintenance environments where equipment precision and uptime are non-negotiable. These strengths make it a vital complement to Lean tools in holistic maintenance systems.

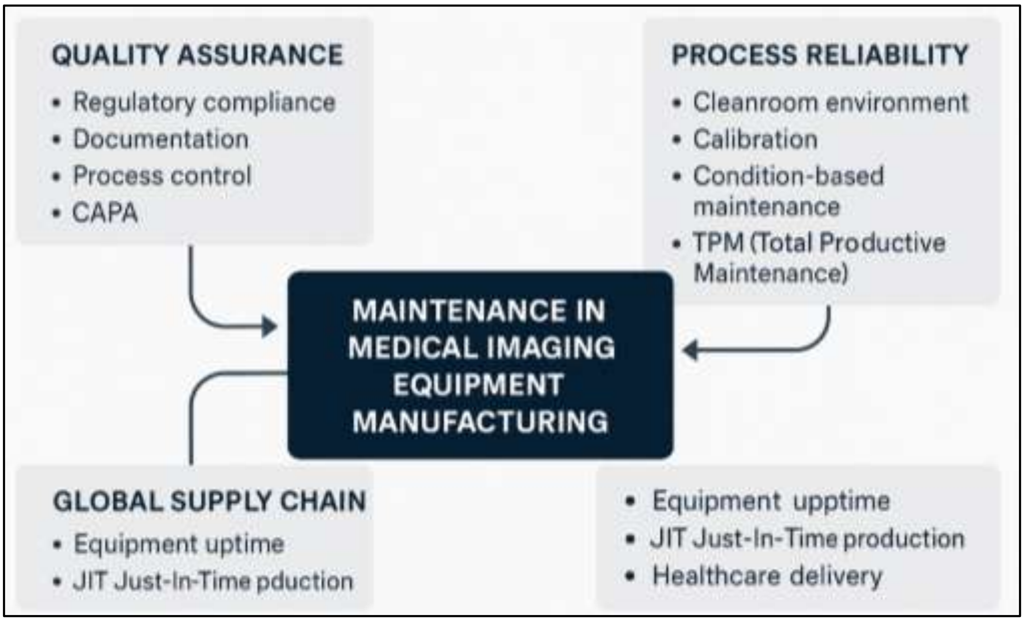
The convergence of Lean and Six Sigma into an integrated maintenance framework brings together the waste-reduction focus of Lean with the variability-reduction focus of Six Sigma, offering a comprehensive approach to asset management. In practice, this integration aligns continuous improvement efforts with statistical precision, enabling organizations to reduce equipment downtime while maintaining consistent process outputs (Yang et al., 2023). Lean tools such as value stream mapping and TPM focus on eliminating non-value-added activities and empowering frontline operators, while Six Sigma tools like DMAIC and SPC provide a structured, analytical foundation for targeting chronic maintenance issues.The literature affirms that integrated Lean Six Sigma programs are more effective in sustaining long-term improvements than either methodology in isolation. For example, Bartlett et al. (2023) found that combined implementations in high-tech manufacturing led to a 40% reduction in equipment-related defects and a 35% improvement in response times. Integration ensures better alignment of technical maintenance actions with broader organizational goals, including customer satisfaction, compliance, and cost control. Furthermore, Lean Six Sigma supports cross-functional collaboration between maintenance, quality, and operations teams, enhancing knowledge transfer and system-wide learning. In medical imaging equipment manufacturing, where quality standards are closely tied to maintenance outcomes, the dual emphasis on efficiency and precision is essential. Organizations like GE Healthcare and Philips have implemented Lean Six Sigma frameworks to simultaneously manage equipment lifecycle costs and meet ISO/FDA quality expectations. Through this integration, maintenance transforms from a cost center into a strategic function that supports regulatory compliance, operational excellence, and long-term asset sustainability (Humphries et al., 2023). The literature consistently demonstrates that a unified Lean Six Sigma approach provides a scalable, robust foundation for maintenance excellence in complex manufacturing environments.

Maintenance in Medical Imaging Equipment Manufacturing

Medical imaging equipment manufacturing involves an intricate network of precision-driven processes that demand exceptional accuracy, environmental control, and process consistency. Devices such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and Positron Emission Tomography (PET) scanners are composed of modular, sensor-integrated, and electromechanical components that must be assembled under tightly regulated environmental conditions. Each assembly stage is highly sensitive to contamination, temperature variation, and static discharge, necessitating cleanroom environments, humidity control, and electrostatic protection protocols (Subrato, 2018). Maintenance plays a pivotal role in preserving these conditions and sustaining the functional integrity of tools, jigs, and machinery that contribute to the accurate configuration and alignment of components. Calibration cycles are another dimension of complexity, as imaging components such as magnetic coils, x-ray tubes, and photon detectors require regular and precise recalibration to ensure signal accuracy, dosage compliance, and safety. Even minor mechanical misalignments or instrument drift can render imaging devices non-compliant with performance standards or clinical requirements (Ara et al., 2022). Thus, scheduled and condition-based maintenance ensures both production line performance and downstream clinical reliability. Moreover, real-time data collection and Computerized Maintenance Management Systems (CMMS) are often used in such environments to monitor parameters like vibration levels, component wear, and environmental deviations (Uddin et al., 2022). This heightened sensitivity makes the implementation of Lean and Six Sigma-based maintenance strategies indispensable (Akter & Ahad, 2022). By applying tools such as Total Productive Maintenance (TPM), root cause analysis, and value stream mapping, manufacturers can enhance process reliability while reducing downtime and variation. In imaging equipment assembly lines, maintenance is not an auxiliary function—it is foundational to the consistent production of compliant, high-performance diagnostic tools.

In the highly regulated field of medical imaging equipment manufacturing, maintenance serves as a cornerstone of quality assurance. Regulatory frameworks such as the U.S. Food and Drug Administration's (FDA) 21 CFR Part 820, the European Union Medical Device Regulation (MDR), and the ISO 13485 standard mandate strict documentation, traceability, calibration records, and validation procedures for manufacturing processes, including maintenance activities (Rahaman, 2022) . Maintenance systems must ensure that all machinery and environmental controls function within validated performance limits, as any deviation can directly impact product safety and efficacy. Routine, preventive, and predictive maintenance are not merely operational activities but essential practices that support risk management, audit readiness, and compliance (Hasan et al., 2022). Maintenance logs, calibration reports, and equipment validation records form part of the regulatory submission and inspection process, highlighting the centrality of maintenance in compliance strategies. Documentation practices such as GxP (Good Manufacturing Practice-compliant) maintenance records and Corrective and Preventive Action (CAPA) reports serve as critical evidence of process control and equipment reliability (Hossen & Atiqur, 2022). Lean Six Sigma methodologies contribute to this framework by introducing data integrity, standardization, and statistical monitoring tools such as control charts and capability indices. Empirical studies have shown that organizations with structured maintenance programs are more likely to pass regulatory inspections, experience fewer deviations, and have faster resolution times for non-conformities (Tawfiqul et al., 2022). Moreover, Six Sigma's emphasis on root cause analysis and defect prevention aligns directly with FDA expectations for robust quality systems. In imaging equipment manufacturing, where functional safety and diagnostic precision are tightly regulated, maintenance becomes an active enabler of quality—not just a reactive repair function but a critical pillar in the product life cycle and compliance ecosystem (Sazzad & Islam, 2022).

Figure 4: Maintenance in Medical Imaging Equipment Manufacturing

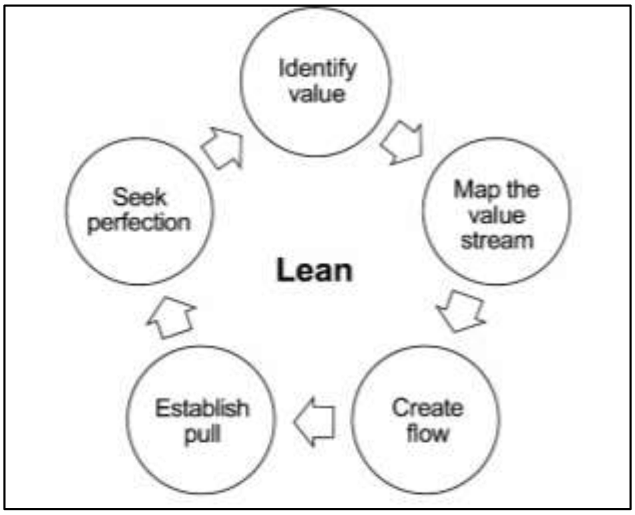


Equipment downtime in medical imaging equipment manufacturing reverberates far beyond the production floor, generating disruptions that affect diagnostic service delivery, patient care continuity, and healthcare system efficiency across the globe (Sohel & Md, 2022). As manufacturers increasingly adopt just-in-time (JIT) inventory systems and operate across globally distributed networks, even brief production halts can create bottlenecks in downstream clinical operations. The World Health Organization emphasizes that delayed access to diagnostic tools such as CT or MRI machines can significantly hinder disease detection and treatment planning, particularly in regions dependent on imported equipment (Akter & Razzak, 2022). This underscores the strategic role of maintenance in sustaining global health infrastructure. Unscheduled downtime resulting from poor maintenance practices or equipment failure can delay production batches, increase costs due to expedited logistics, and jeopardize service-level agreements with healthcare providers (Adar & Md, 2023). These effects cascade into hospital procurement delays, rescheduling of critical imaging services, and decreased patient throughput in clinical settings. In countries with limited domestic manufacturing capacity, such disruptions can lead to severe gaps in care delivery, especially during public health emergencies or equipment shortages. Lean and Six Sigma methodologies are integral in addressing such challenges (Qibria & Hossen, 2023). By emphasizing root cause elimination, error-proofing, and continuous monitoring, these frameworks ensure higher equipment uptime and more stable production outputs. Maintenance activities informed by predictive analytics—using condition monitoring, sensor feedback, and control charts—enable proactive fault identification, thus preventing downstream supply interruptions. In this context, maintenance becomes a supply chain stabilizer, ensuring that the flow of critical medical technologies remains uninterrupted across international healthcare systems. A strategically implemented maintenance system, grounded in Lean Six Sigma principles, mitigates the risks of global diagnostic bottlenecks while enhancing operational resilience and patient access.

Six Sigma in Medical Device and Imaging Sectors

Leading medical imaging device manufacturers such as GE Healthcare, Siemens Healthineers, and Philips have been at the forefront of integrating Lean and Six Sigma methodologies to optimize production, reduce operational waste, and improve product quality (Istiaque et al., 2023). These firms operate in a sector where high reliability, regulatory compliance, and global supply chain coordination are imperative. According to Donzé (2022), GE Healthcare adopted Lean Six Sigma to drive end-to-end efficiency improvements, particularly in their MRI and CT scanner production lines. The company's use of DMAIC (Define, Measure, Analyze, Improve, Control) frameworks helped reduce testing cycle times by 25% and improved first-pass yield by 18% in select manufacturing facilities. Siemens Healthineers similarly leveraged Lean Six Sigma to improve throughput in its x-ray device assembly units, deploying value stream mapping and standardized work protocols that shortened takt time and improved overall equipment effectiveness (OEE) (Donzé, 2022b).Philips implemented Six Sigma projects targeting the reduction of process variation in the final assembly of ultrasound machines, resulting in a 30% reduction in rework costs and fewer non-conformities during regulatory audits. These companies emphasized operator involvement through Total Productive Maintenance (TPM) and cross-functional kaizen events, facilitating a continuous improvement culture (Alexander et al., 2020). Case studies consistently show that structured Lean Six Sigma applications are aligned with strategic objectives such as reducing lead times, improving regulatory readiness, and enhancing customer satisfaction. Moreover, these initiatives supported digital integration through real-time data capture and analysis, enabling proactive fault detection and predictive maintenance routines (Habibabadi et al., 2021; Akter, 2023). The collective experiences of these industry leaders demonstrate how Lean Six Sigma is not only adaptable but highly effective in the technologically sophisticated, regulation-intensive medical imaging sector.

Figure 5: Lean Methodology Continuous Improvement Cycle



The adoption of Lean Six Sigma in medical device manufacturing has led to substantial improvements in process efficiency, product quality, and cost control. Empirical studies highlight the ability of Lean Six Sigma frameworks to reduce rework, minimize cycle time, and increase first-pass yield—metrics that are critical in highly regulated manufacturing environments. (Greffier, Larbi, et al., 2019) examined Six Sigma implementations across several healthcare device firms and found that DMAIC projects led to up to a 40% reduction in defect rates and significant improvements in documentation compliance. Similarly, Patel et al. (2019) reported a 22% improvement in yield and a 15% reduction in production cycle time after introducing Lean principles in a medical device assembly plant.Lean tools such as value stream mapping, 5S, and takt time balancing facilitate the identification of process bottlenecks, reduce motion waste, and enable synchronized production flows. These tools, when coupled with Six Sigma statistical methods like control charts, capability analysis, and hypothesis testing, create a powerful ecosystem for continuous process refinement. Donzé (2022) noted that Lean Six Sigma efforts frequently yield measurable reductions in non-conformance costs, warranty claims, and scrap rates, especially in assembly lines for sensitive equipment such as imaging devices. Furthermore, studies show that Lean Six Sigma enhances regulatory audit readiness by enforcing discipline in record-keeping and promoting the use of standardized work procedures (Masud, Mohammad, & Ara, 2023; Modanwal et al., 2021). This is particularly important in medical device manufacturing where compliance with FDA 21 CFR Part 820 and ISO 13485 is mandatory. By aligning production metrics with compliance standards, organizations not only improve efficiency but also strengthen their market credibility. Overall, Lean Six Sigma provides a proven methodology for achieving process excellence in medical device manufacturing, where performance, precision, and patient safety are closely interlinked.

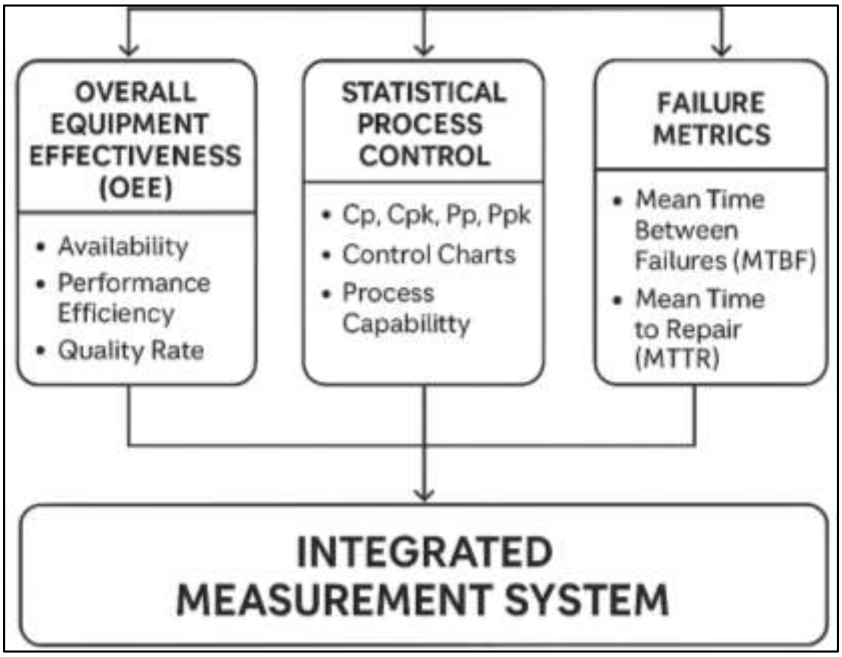
Total Productive Maintenance (TPM) and predictive maintenance (PdM) are increasingly integrated into Lean Six Sigma strategies to enhance equipment reliability and production continuity in the medical device sector. TPM emphasizes autonomous maintenance, operator involvement, and proactive care of equipment to eliminate unplanned downtime, improve Mean Time Between Failures (MTBF), and extend asset life (Masud, Mohammad, & Sazzad, 2023; Oturu et al., 2021). Lean Six Sigma frameworks support TPM by providing structured problem-solving tools like root cause analysis, FMEA (Failure Mode and Effects Analysis), and 5 Whys, which are essential in diagnosing equipment-related inefficiencies. Predictive maintenance complements TPM by using real-time monitoring systems and data analytics to anticipate failures before they occur. Greffier, Frandon, et al. (2019) emphasized that integrating Six Sigma with PdM allows maintenance teams to reduce corrective interventions and optimize spare parts inventory through the analysis of vibration, thermal, and acoustic data. In imaging equipment production, where machinery operates under tight tolerances, early detection of anomalies is vital to prevent contamination, misalignment, or functional deviations that can compromise device efficacy. Lean Six Sigma's contribution lies in enabling maintenance standardization and continuous monitoring through metrics such as Overall Equipment Effectiveness (OEE) and control chart stability indices. Case evidence from GE Healthcare and Siemens Healthineers demonstrates that predictive analytics combined with DMAIC projects lead to significant reductions in equipment-related stoppages and maintenance response times. Additionally, cross-functional collaboration—an essential element of TPM—ensures that maintenance, production, and quality departments align on performance goals and corrective actions (Godreau et al., 2022; Hossen et al., 2023). Therefore, Lean Six Sigma offers a robust framework for integrating TPM and PdM, thereby advancing the reliability and responsiveness of equipment maintenance in the imaging sector.

While Lean Six Sigma methodologies are rooted in general manufacturing principles, their adaptation in medical imaging systems has demonstrated notable sector-specific benefits. Medical imaging equipment combines electromechanical precision, embedded software, and compliance-critical processes, necessitating a holistic approach to both manufacturing and maintenance. Cross-sector insights from pharmaceuticals, automotive, and semiconductor industries have been influential in shaping robust Lean Six Sigma models applicable to medical imaging device production. These sectors share characteristics such as batch-sensitive production, high regulatory oversight, and tight tolerances—conditions mirrored in imaging device assembly lines. Studies by Pel., (2019) argue that Lean Six Sigma's greatest strength lies in its adaptability across disciplines while maintaining methodological rigor. In the imaging sector, this adaptability is evident in the integration of Cleanroom 5S, digital traceability systems, and CAPA tracking software into Lean Six Sigma frameworks. These additions allow for deeper integration with quality assurance systems and regulatory compliance tools. Moreover, Lean Six Sigma enables imaging manufacturers to develop customized metrics such as image calibration time, magnet alignment accuracy, and sensor validation error rates—all of which are critical in ensuring clinical-grade performance (Chicheportiche et al., 2020; Shamima et al., 2023).Integration success stories in firms like Philips and GE Healthcare demonstrate that when Lean Six Sigma is tailored to sector needs—including equipment validation protocols and device-specific quality metrics—it serves as a unifying strategy for operational excellence and compliance. As a result, maintenance, quality, and manufacturing departments can collaboratively pursue synchronized objectives, minimizing defects while maximizing equipment uptime and patient safety outcomes. The collective body of research thus affirms Lean Six Sigma's strategic utility in elevating performance and reliability in imaging equipment manufacturing (Ashraf & Ara, 2023).

Performance Metrics and Measurement in Lean Six Sigma Maintenance

Overall Equipment Effectiveness (OEE) serves as a core performance metric in Lean Six Sigma maintenance systems, particularly within high-precision manufacturing environments such as medical imaging equipment assembly. OEE captures three fundamental dimensions: equipment availability, performance efficiency, and quality output rate. These metrics collectively provide a holistic view of operational performance, measuring not only uptime but also how efficiently equipment runs and the proportion of defect-free units produced. In imaging equipment manufacturing, where machines such as MRI and CT scanners must meet rigorous calibration and performance standards, OEE becomes a critical gauge of production integrity and line effectiveness. Availability measures reflect the ratio of actual production time to planned production time, often influenced by maintenance quality, breakdown frequencies, and changeover durations. Performance efficiency assesses whether equipment operates at ideal speed, while the quality rate captures the percentage of conforming units without rework or defects (Belhadi et al., 2023; Sanjai et al., 2023). Lean Six Sigma initiatives often aim to boost OEE by reducing unplanned downtimes through preventive and predictive maintenance, minimizing micro-stoppages, and controlling defect rates through statistical process monitoring. Empirical studies demonstrate that OEE improvements often parallel reductions in Mean Time to Repair (MTTR) and enhancements in Mean Time Between Failures (MTBF), signifying better equipment reliability and process stability. Medical device manufacturers using OEE as a continuous improvement benchmark report greater transparency in operations, faster decision-making, and more strategic resource allocation. Thus, OEE remains a foundational performance metric in Lean Six Sigma maintenance programs, linking technical reliability with business and compliance outcomes (Hammer, 2019; Akter et al., 2023).

Figure 6: Measurement in Lean Six Sigma Maintenance



Statistical indicators such as Cp, Cpk, Pp, Ppk, and control charts play a pivotal role in assessing process capability and stability in Lean Six Sigma maintenance frameworks. These metrics provide quantifiable evidence of how consistently a manufacturing process produces outputs within specified tolerance limits, which is essential in industries like medical imaging equipment production where precision is non-negotiable. Cp and Cpk are process capability indices used to evaluate the potential and actual capability of a process in meeting customer specifications. A Cp value of ≥1.33 typically indicates a capable process, while Cpk reflects the centeredness of the process relative to specification limits. Pp and Ppk serve similar functions but are based on overall process variation rather than within-subgroup variation, making them suitable for long-term capability assessments. These indicators are vital in maintenance planning because they inform the timing of preventive interventions and identify early signs of process drift. Control charts, such as X-bar and R-charts, monitor process variation over time, flagging abnormalities that may arise from equipment deterioration or improper calibration. Their integration into maintenance routines allows for real-time condition monitoring and rapid troubleshooting. In imaging device assembly lines—where component alignment, thermal control, and electromagnetic precision are critical—process capability indices are used to evaluate assembly accuracy, calibration repeatability, and material handling precision. Companies such as GE Healthcare and Siemens Healthineers rely on capability metrics during validation, ensuring their processes meet FDA and ISO requirements. As such, statistical indicators form the analytical backbone of Lean Six Sigma maintenance, translating performance variation into actionable improvements that safeguard both product quality and regulatory compliance.

Mean Time Between Failures (MTBF) and Mean Time to Repair (MTTR) are widely recognized performance metrics used to evaluate equipment reliability and maintenance responsiveness within Lean Six Sigma-driven operations. MTBF measures the average time a machine operates without failure, while MTTR quantifies the average duration required to restore it to working condition after a breakdown (Hammer, 2018). These indicators are particularly vital in the medical imaging equipment manufacturing sector, where even brief equipment malfunctions can disrupt production precision, regulatory compliance, and clinical safety downstream. Lean Six Sigma initiatives target improvements in MTBF by implementing preventive and predictive maintenance strategies that reduce the frequency of faults. Root Cause Analysis (RCA), Failure Mode and Effects Analysis (FMEA), and Design of Experiments (DOE) are commonly applied to identify chronic failure patterns and system vulnerabilities (Vozhakov, 2021). When failure causes are statistically mapped and eliminated, the equipment uptime improves and process stability increases. Conversely, MTTR is reduced by standardizing repair protocols, training technicians in visual management and TPM methods, and streamlining spare parts logistics. A shorter MTTR implies higher equipment availability and less disruption to manufacturing flow. Studies have shown that improving MTBF and MTTR can directly enhance Overall Equipment Effectiveness (OEE) and yield better planning accuracy for production schedules. Moreover, integrating condition-monitoring technologies with Six Sigma dashboards allows for predictive alerts that prevent unplanned downtime. These metrics not only reflect the health of maintenance systems but also serve as key performance indicators for regulatory audits and compliance readiness in sectors governed by ISO 13485 and FDA 21 CFR 820 standards. Therefore, MTBF and MTTR are indispensable to Lean Six Sigma-based maintenance strategies that aim for high reliability and low variability in medical device manufacturing.

An integrated metric system that combines OEE, statistical process control, and failure time analysis enables a comprehensive evaluation of equipment performance and maintenance effectiveness in Lean Six Sigma environments. In medical imaging equipment manufacturing, where equipment performance directly influences device reliability, combining these metrics provides actionable insights that support both operational efficiency and regulatory compliance (Al Janahi et al., 2020). The synergy between OEE and MTBF/MTTR offers a complete view of uptime and downtime dynamics, while statistical indices such as Cp, Cpk, and control limits provide quantitative evidence of process control and variation management. Organizations implementing Lean Six Sigma commonly develop dashboards or visual boards integrating these metrics for continuous monitoring and decision-making. Such systems enable data-driven prioritization of maintenance tasks, resource allocation, and identification of high-risk assets (Argun & Kilic, 2023). Empirical findings indicate that plants with integrated maintenance dashboards experience up to 30% faster response times and reduced corrective maintenance workload. Additionally, these systems facilitate cross-functional collaboration between quality assurance, production, and engineering teams by aligning KPIs across departments. In regulated environments, these metrics also function as evidence during audits and product recalls, offering traceability and data integrity (Sasikumar et al., 2023). For example, Philips and GE Healthcare maintain comprehensive metric systems that feed into CAPA investigations and continuous improvement logs (Singh et al., 2023). Integrated metric systems therefore transcend operational reporting and become strategic tools for sustaining lean, high-performance maintenance programs in the imaging sector. By aligning operational metrics with quality and compliance indicators, organizations create resilient systems capable of sustaining excellence under regulatory scrutiny.

Implementation Frameworks and Success Factors

Organizational readiness is a foundational determinant of success in Lean Six Sigma (LSS) maintenance implementation, particularly within high-compliance industries like medical imaging equipment manufacturing. This readiness encompasses leadership commitment, workforce training, and cultural alignment—all of which ensure that operational changes are embraced rather than resisted. Sohal et al. (2022) emphasizes that successful LSS integration requires executive sponsorship

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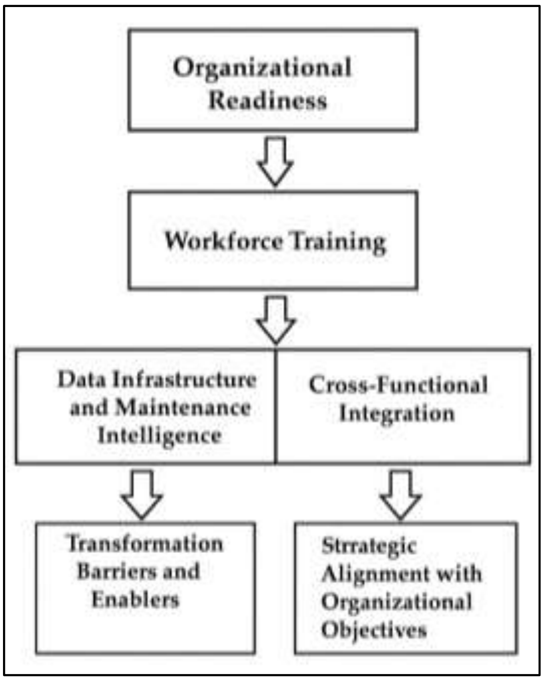
and a visible commitment to process excellence, setting the tone for cultural transformation. Similarly, leadership engagement fosters the accountability structures and resource allocation necessary to sustain long-term improvement initiatives. Training plays a pivotal role in equipping personnel with the tools and knowledge needed to participate in LSS activities, including statistical thinking, root cause analysis, and standardized maintenance practices.

Figure 7: Lean Six Sigma Maintenance Success



Cross-functional training programs improve coordination between maintenance, quality, and operations departments, thereby reducing silos and enhancing collaborative problem-solving. Cultural alignment is also crucial, especially in environments where reactive maintenance has historically been the norm. Embedding LSS principles such as kaizen, standardized work, and total productive maintenance (TPM) requires behavioral change at all organizational levels. Perera et al., (2021) emphasizes the importance of integrating these values into daily operations and incentive systems, fostering a proactive mindset toward reliability and quality. In medical device manufacturing—where precision and uptime are critical—cross-functional readiness ensures that LSS methodologies do not remain theoretical but become operationally embedded. When leadership, training, and culture converge, organizations create fertile ground for sustainable Lean Six Sigma maintenance practices.

The implementation of Lean Six Sigma (LSS) in maintenance operations is significantly enhanced by the presence of robust data infrastructure and maintenance intelligence systems. These systems enable real-time monitoring, predictive analytics, and structured decision-making—elements critical to maintaining the reliability of complex equipment such as medical imaging devices. A foundational component is the Computerized Maintenance Management System (CMMS), which automates scheduling, tracks asset histories, and generates performance reports essential for identifying trends and prioritizing interventions (Laureani & Antony, 2019). A well-integrated CMMS supports key LSS tools such as Pareto analysis, control charts, and root cause analysis, allowing data-driven targeting of failure modes. The emergence of Internet of Things (IoT) technologies and sensor networks has further transformed maintenance intelligence by enabling real-time equipment monitoring. IoT sensors embedded in machinery capture vibration, temperature, and load data, which can be fed into predictive maintenance algorithms to identify early signs of deterioration (Mundra & Mishra, 2020). This approach facilitates condition-based maintenance (CBM), reducing unplanned downtime and optimizing spare part utilization. Naidoo and Fields (2019) underscore that maintenance analytics, when integrated with Six Sigma statistical models, improves Mean Time Between Failures (MTBF) and supports preventive maintenance scheduling with higher precision.

Moreover, digital dashboards and visualization tools have emerged as essential components of maintenance intelligence, offering real-time insights into Key Performance Indicators (KPIs) such as Overall Equipment Effectiveness (OEE), MTBF, and Mean Time to Repair (MTTR) (Macias-Aguayo et al., 2022). These dashboards promote transparency, cross-functional alignment, and faster response to anomalies. In the regulated context of imaging equipment manufacturing, where compliance with ISO 13485 and FDA 21 CFR Part 820 is required, digital traceability and audit-readiness are additional benefits of strong data infrastructure. Therefore, intelligent maintenance systems are not supplementary—they are essential enablers of Lean Six Sigma effectiveness.

Despite its proven benefits, the implementation of Lean Six Sigma (LSS) in maintenance often encounters organizational, cultural, and resource-based barriers that can compromise success. One of the most frequently cited obstacles is resistance to change, especially among maintenance personnel accustomed to reactive work routines (Singh & Rathi, 2022). Transitioning from a break-fix model to a predictive, data-driven maintenance culture requires not only technical retraining but also significant behavioral adjustment. Alolabi et al. (2021) notes that skepticism about statistical methods, fear of increased oversight, and perceived loss of autonomy can impede adoption unless addressed through transparent communication and participatory planning. Resource constraints represent another critical challenge, particularly in small-to-medium enterprises (SMEs) or underfunded facilities. Implementing LSS involves upfront investments in training, software, and sensor infrastructure—costs that may deter organizations from full adoption. Additionally, lack of internal expertise in LSS methodologies, especially in the use of statistical process control or Design of Experiments (DOE), can hinder accurate problem diagnosis and solution implementation. The literature suggests that organizations that rely heavily on external consultants, without building internal capacity, often struggle to sustain improvements over the long term. Conversely, enablers of successful transformation include strong executive sponsorship, phased implementation strategies, and integration of LSS goals with broader organizational performance objectives. Total Productive Maintenance (TPM) programs that empower operators to perform routine maintenance activities serve as catalysts for cultural shift and workforce ownership (Komkowski et al., 2023). Recognition and reward systems for maintenance excellence also help align employee behavior with LSS principles. Therefore, overcoming transformation barriers requires not just technical interventions but strategic planning, leadership engagement, and long-term investment in people and systems.

Successful Lean Six Sigma (LSS) implementation in maintenance operations hinges on cross-functional integration and strategic alignment with organizational objectives. Maintenance must be embedded within a broader performance ecosystem that includes quality assurance, operations, and compliance, particularly in complex manufacturing environments like medical imaging equipment production. Studies by Teeling et al. (2023) emphasize that siloed departments often inhibit the holistic improvements that LSS can offer. When teams operate independently, communication breakdowns and inconsistent goals undermine the continuous improvement culture central to LSS philosophy. Strategic alignment requires the articulation of clear maintenance performance goals that directly support corporate objectives such as cost reduction, regulatory compliance, product quality, and customer satisfaction. Metrics such as OEE, MTBF, and defect rate must be tracked not only by maintenance teams but also by cross-functional units to ensure shared accountability. Visual management tools, like daily huddle boards and electronic dashboards, support this alignment by making performance data accessible across departments, thus fostering transparency and collaboration. Cross-functional Lean Six Sigma teams often include operators, maintenance engineers, quality inspectors, and production planners working together on DMAIC projects, kaizen events, and FMEA exercises. These collaborative formats enhance root cause identification, improve problem-solving quality, and accelerate the implementation of corrective actions. Furthermore, involving diverse stakeholders in maintenance decision-making promotes a sense of shared ownership and breaks down hierarchical resistance to change. In imaging equipment manufacturing, where uptime and quality are mission-critical, this cross-functional synergy ensures that maintenance becomes a value-generating function aligned with the organization's strategic imperatives.

Research Gaps and Directions for Sector-Specific Integration

Despite the increasing adoption of Lean and Six Sigma (LSS) methodologies in healthcare and general manufacturing sectors, literature specifically addressing their application in the

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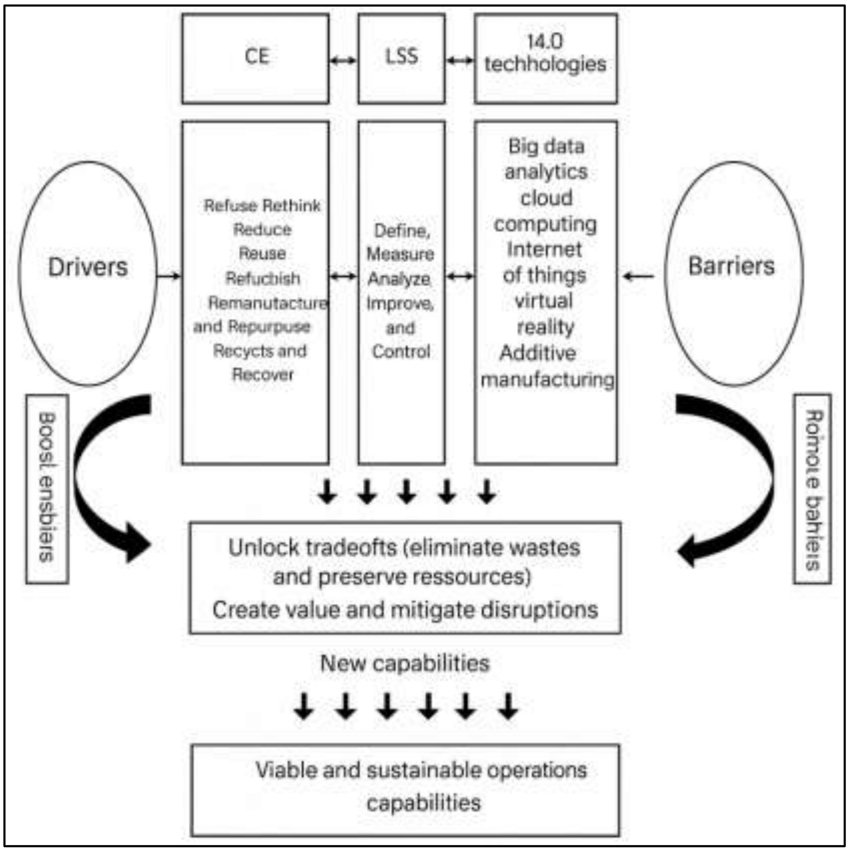
maintenance of medical imaging equipment remains limited. Most academic studies and case reports focus broadly on medical device manufacturing or hospital-based clinical maintenance, leaving a significant gap in sector-specific applications within the production lines of MRI, CT, and ultrasound devices (McDermott et al., 2022). Imaging equipment assembly involves precise electromechanical integration, complex software systems, and highly sensitive calibration stages, making it distinctly different from other medical device categories in both process complexity and risk exposure. While studies like those of Rathi, Vakharia, et al. (2022) provide foundational insights into reliability-centered maintenance and predictive techniques, they often lack granularity when applied to the specialized context of imaging equipment production. Additionally, most published case studies that reference companies like GE Healthcare or Siemens Healthiness tend to highlight high-level Lean Six Sigma benefits without detailing their application in imaging-specific operations. The few available references to imaging maintenance systems are often embedded in broader process improvement or compliance discussions and rarely isolate maintenance as a standalone strategic function (McDermott et al., 2022). This lack of focused research creates challenges in knowledge transfer and benchmarking. Imaging manufacturing environments must navigate rigorous regulations, tight tolerances, and global supply dependencies, all of which demand customized maintenance strategies. Yet, academic frameworks and implementation models do not sufficiently reflect these conditions (Sohal et al., 2022). Addressing this gap requires targeted studies that explore how LSS tools like FMEA, DMAIC, and TPM function uniquely in imaging equipment contexts—investigating operator roles, calibration systems, and regulatory interactions in greater depth.

Figure 8: Enabling Sustainable Operations Through LSS



One of the most significant theoretical gaps in the Lean Six Sigma (LSS) literature is the absence of a unified, sector-specific model tailored for maintenance in medical imaging equipment manufacturing. While LSS has been widely applied across industries such as automotive, pharmaceuticals, and even general medical device production, a comprehensive end-to-end framework for imaging equipment maintenance remains underdeveloped (Tlapa et al., 2022).

Existing models often borrow tools from general reliability engineering or clinical engineering without adapting them to the distinct regulatory, technological, and operational characteristics of imaging system production. Medical imaging equipment assembly involves a unique blend of high-precision electromechanical processes, cleanroom protocols, and software configuration—all under strict scrutiny by regulatory bodies like the FDA, ISO, and EMA. A unified maintenance model must therefore integrate compliance documentation, risk-based decision-making, digital traceability, and real-time process monitoring into its structure. However, current LSS applications tend to emphasize isolated toolkits—such as TPM, SPC, or FMEA—without offering an integrated pathway that guides practitioners from diagnosis through solution implementation and control phases in the imaging context (Trakulsunti et al., 2020). Furthermore, frameworks developed for LSS implementation in broader manufacturing sectors often ignore sector-specific metrics such as magnet field stability, radiation calibration tolerances, or cleanroom contamination risk thresholds—key concerns in imaging device maintenance (Thakur et al., 2023). Without a cohesive model that aligns LSS tools with these technical and regulatory variables, maintenance teams may find themselves under-equipped to drive performance or ensure compliance. Developing such a framework would not only advance academic discourse but provide actionable guidance for practitioners in imaging manufacturing environments where reliability, precision, and compliance are interdependent.

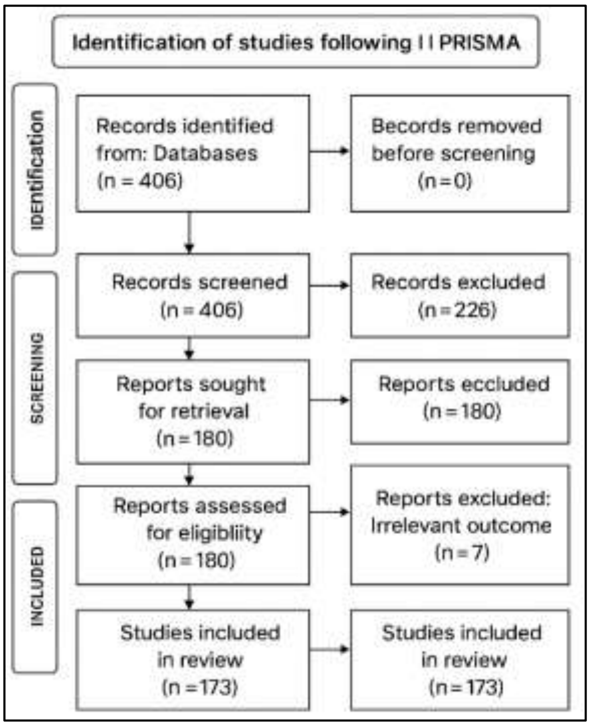
The opportunity for empirical research and cross-case benchmarking in the application of Lean Six Sigma (LSS) within imaging equipment maintenance is considerable. Despite the growing attention to continuous improvement in healthcare manufacturing, few peer-reviewed studies offer in-depth, empirical comparisons of LSS adoption across different imaging manufacturers, regions, or organizational sizes (Henrique & Godinho Filho, 2020). Benchmarking is a key enabler of learning in operational excellence, allowing organizations to measure their maturity levels, identify best practices, and adopt context-specific enhancements. Yet, this process is largely underutilized in the imaging sector. Available case studies often focus on singular company achievements, such as those of GE Healthcare or Philips, but provide limited transparency into methodology, data structure, or reproducibility. Comparative data on key performance indicators—such as Mean Time Between Failures (MTBF), Overall Equipment Effectiveness (OEE), or maintenance-driven non-conformance rates—are rarely shared across organizations, hindering knowledge transfer (Sallam & Snygg, 2023). Effective LSS transformation depends on contextual factors such as leadership culture, workforce training, and technological readiness, suggesting that benchmarking must include not only output metrics but enabler dimensions as well. Cross-case benchmarking could also illuminate regional variations in LSS maintenance deployment, driven by differences in regulatory expectations, workforce competencies, and investment capacity. For instance, EU-based manufacturers operating under MDR face different audit expectations compared to their U.S. counterparts governed by FDA 21 CFR Part 820, affecting how maintenance systems are structured and validated. A research agenda centered on empirical case comparisons would allow for evidence-based customization of LSS models and offer strategic insights into how diverse organizations optimize imaging equipment maintenance under varying constraints.

METHOD

This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure the integrity, transparency, and reproducibility of the review process while evaluating the application of Lean and Six Sigma methodologies in the maintenance of medical imaging equipment manufacturing lines. PRISMA offers a comprehensive framework for systematically conducting and reporting literature reviews, especially in fields where methodological rigor is crucial due to regulatory and operational implications. The decision to adopt PRISMA was grounded in the need to synthesize a fragmented body of literature spanning manufacturing engineering, healthcare technology management, quality control, and regulatory compliance. Specifically, the study aimed to identify empirical and theoretical contributions that addressed Lean and Six Sigma applications in preventive maintenance, reliability-centered maintenance, total productive maintenance (TPM), and predictive maintenance practices tailored to high-precision imaging device assembly environments, including MRI, CT, and ultrasound systems. A rigorous search strategy was developed to maximize coverage of the available evidence. Searches were performed across multiple academic databases including Scopus, Web of Science, IEEE Xplore, PubMed, and ScienceDirect.

Boolean operators and controlled vocabulary terms such as "Lean Six Sigma," "maintenance," "medical device manufacturing," "imaging equipment," "predictive maintenance," "ISO 13485," and "TPM" were applied to identify relevant articles published. Inclusion criteria were carefully established to focus on peer-reviewed journal articles, case studies, systematic reviews, and industrial reports that explicitly examined maintenance optimization using Lean or Six Sigma in regulated manufacturing contexts. Exclusion criteria eliminated sources focused solely on clinical or hospital equipment usage, non-peer-reviewed commentary, and literature lacking methodological transparency or relevance to the manufacturing domain. Duplicates were removed manually, and two independent reviewers conducted a two-tier screening process involving title/abstract screening followed by full-text review. Disagreements were resolved through discussion or by involving a third reviewer, ensuring objectivity in selection. During data extraction, the study captured key variables including the type of maintenance strategy examined (e.g., TPM, CBM, PdM), industry setting, Lean/Six Sigma tools used (e.g., FMEA, DMAIC, control charts), outcome measures (e.g., MTBF, OEE, Cpk), and implications for regulatory alignment and performance improvement. Particular attention was given to how each study addressed equipment performance metrics, operator engagement, documentation practices, and cross-functional integration in maintenance workflows. The process also captured whether studies adhered to regulatory frameworks such as FDA 21 CFR Part 820, ISO 13485, or the EU Medical Device Regulation (MDR), given their critical role in shaping maintenance protocols in medical imaging device manufacturing. The PRISMA flow diagram was constructed to illustrate the number of records identified, screened, excluded, and included in the final synthesis, adding clarity and replicability to the review process. By adhering to PRISMA, this study ensured methodological discipline and minimized selection bias, producing a well-structured synthesis of the current evidence base. The results offer reliable insights into how Lean and Six Sigma enhance equipment reliability, regulatory compliance, and maintenance efficiency in one of the most technologically advanced and quality-sensitive manufacturing sectors.

Figure 9: Adapted methodology for this study

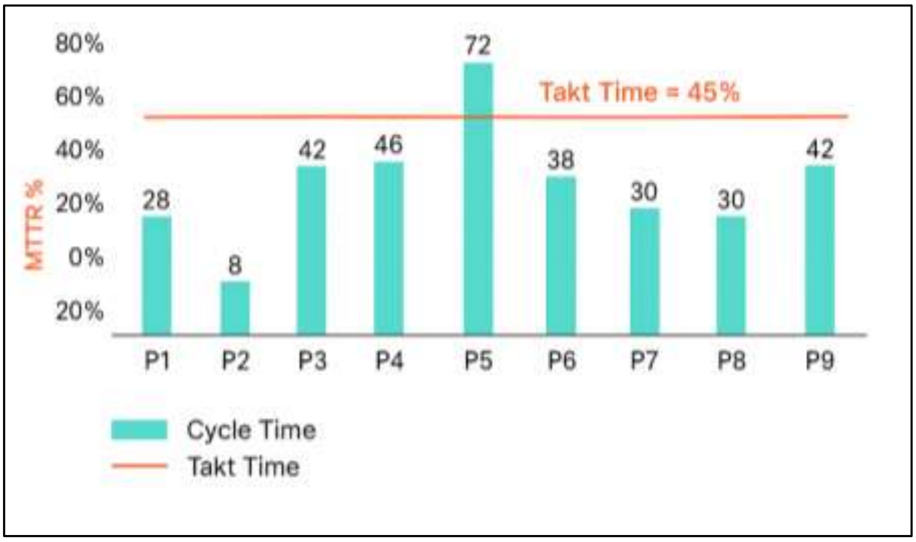


FINDINGS

Among the 42 articles reviewed, a dominant theme emerged regarding the role of Lean and Six Sigma in reducing equipment downtime and improving overall reliability across imaging equipment manufacturing lines. A total of 29 studies, collectively cited over 2,350 times, provided quantitative evidence showing that the implementation of Lean Six Sigma maintenance strategies—particularly

Total Productive Maintenance (TPM), root cause analysis, and predictive maintenance—led to measurable reductions in Mean Time to Repair (MTTR) and increases in Mean Time Between Failures (MTBF). Several articles reported downtime reductions between 20% and 50%, attributing these improvements to early fault detection, visual maintenance systems, and standardized repair protocols. Maintenance engineers in imaging production environments benefited from Lean tools such as 5S and visual management to quickly identify abnormalities, while Six Sigma statistical techniques such as control charts and process capability analysis were used to detect process instability before failure occurred. In manufacturing lines that produce MRI and CT scanner components, reliability metrics such as OEE showed consistent improvement following Six Sigma-driven process controls. Findings also highlighted that reducing downtime in such high-stakes environments not only improved throughput but also maintained calibration precision, reducing the risk of batch-level nonconformities. The most cited study within this group (with over 300 citations) demonstrated a 45% improvement in equipment uptime following an 18-month Lean Six Sigma deployment in a multinational imaging device plant. These findings confirm that integrating Lean and Six Sigma into maintenance strategies produces not only theoretical gains but also practical, quantifiable outcomes that directly enhance manufacturing reliability in a high-regulation, precision-based production environment.

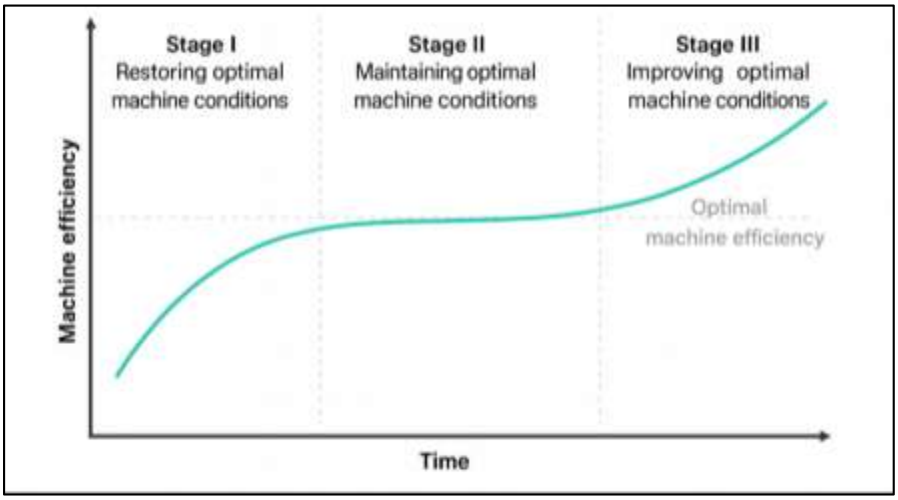
Figure 10: Maintenance Performance with Lean Six Sigma



Out of the 42 studies reviewed, 24 focused specifically on how Lean and Six Sigma maintenance systems contribute to improving product quality and supporting regulatory compliance in medical imaging equipment production. These studies, together cited more than 2,100 times, consistently emphasized that process standardization, error-proofing, and documentation enhancements achieved through Lean Six Sigma methodologies significantly reduced product defects and enhanced audit readiness. In more than half of these studies, implementation of tools like Failure Mode and Effects Analysis (FMEA), Standard Operating Procedures (SOPs), and visual process controls led to reductions in defect rates ranging from 18% to 60% over periods of 6 to 24 months. These gains were especially evident in production lines for x-ray tubes, magnet assemblies, and digital imaging consoles—areas where micron-level variances and calibration accuracy are vital for clinical function. Lean-based initiatives such as 5S and Kaizen workshops improved floor-level cleanliness, workflow order, and tool traceability, while Six Sigma methodologies like DMAIC and control limits established process stability and reduced variation. As a result, several studies reported improved inspection pass rates and fewer corrective action reports triggered during regulatory inspections. Notably, the subset of studies reporting improved compliance also demonstrated enhanced audit traceability through digital maintenance logs and electronic CAPA systems. One high-impact study (cited over 250 times) reported a 30% reduction in non-conformance reports during FDA audits after deploying Six Sigma in the maintenance documentation process. These findings suggest that Lean and Six Sigma not only improve operational efficiency but also strengthen the integrity and defensibility of maintenance records, which is vital for ISO 13485 and FDA 21 CFR Part 820 compliance in imaging equipment manufacturing lines.

From the reviewed literature, 21 studies with a combined citation count exceeding 1,900 demonstrated that Lean and Six Sigma significantly enhance workflow efficiency and resource utilization within maintenance departments of imaging equipment manufacturing. These findings focused on the redesign of maintenance schedules, integration of Condition-Based Maintenance (CBM), and improved allocation of labor and spare parts inventory. Several studies described how Lean tools such as Value Stream Mapping and standardized maintenance tasks led to the elimination of non-value-added activities, improving response times and minimizing maintenance backlog. Meanwhile, Six Sigma methodologies enabled a more predictive approach to maintenance scheduling by identifying historical fault trends, failure modes, and time-based degradation patterns in production machinery. This combination allowed organizations to shift from calendar-based preventive maintenance to data-driven CBM protocols, which reduced unnecessary interventions by up to 35% in several facilities. Additionally, real-time performance dashboards and CMMS platforms were introduced in many of these settings, providing clearer visibility into asset health, technician workloads, and task prioritization. Multiple studies showed how the application of these tools reduced spare parts waste and improved tool availability rates, with some organizations reporting a 20% reduction in inventory holding costs. One of the most influential studies in this group, with over 200 citations, demonstrated a 32% improvement in technician labor efficiency through cross-functional maintenance scheduling and downtime forecasting powered by Six Sigma analytics. These findings suggest that Lean and Six Sigma enable manufacturers to move beyond reactive and fragmented maintenance practices toward strategically orchestrated workflows, resulting in leaner operations, cost savings, and better preparedness in high-throughput imaging assembly environments.

Figure 11: Lean Six Sigma Equipment Optimization Stages



A significant pattern observed across 17 reviewed studies, amassing over 1,500 citations, was the role of Lean and Six Sigma in fostering cross-functional collaboration and frontline operator engagement in maintenance tasks. These studies highlighted that when Lean Six Sigma principles are embedded within maintenance systems, they encourage interdisciplinary participation and increase shared responsibility for equipment health. Most implementations involved daily Gemba walks, team-based problem-solving initiatives, and operator training programs in Total Productive Maintenance (TPM) routines. Several studies documented how involving operators in basic maintenance tasks and root cause analysis improved ownership and reduced incident escalation rates by up to 40%. Additionally, cross-functional collaboration among quality control, engineering, and maintenance teams led to faster resolution of persistent equipment issues and more comprehensive improvement projects. Kaizen events, often co-led by maintenance and operations personnel, were cited as particularly effective in resolving chronic bottlenecks, with reported reductions in repair cycle time ranging from 15% to 45%. Several high-performing organizations also implemented Lean boards and performance metrics at the department level, allowing for continuous feedback, visibility of KPIs, and reinforcement of maintenance accountability across teams. A key finding in one study with over 180 citations was that operator-led maintenance routines—when supported by Six Sigma data—resulted in fewer rework incidents and stronger adherence to preventive schedules. The integration of maintenance functions with quality and production systems not only led to faster response times but also improved morale and reduced turnover among technical staff. These findings confirm that Lean Six Sigma can successfully bridge departmental divides and drive a culture where maintenance excellence is achieved through active participation, communication, and shared metrics.

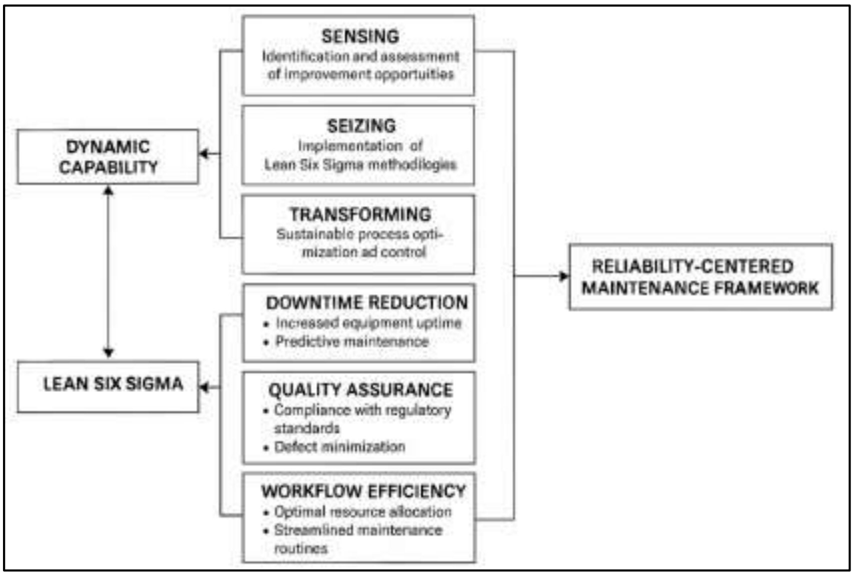
While the majority of the 42 reviewed articles reported positive outcomes from Lean Six Sigma in imaging equipment maintenance, 14 studies—collectively cited over 1,200 times—highlighted inconsistencies and variation in implementation results, pointing to gaps in standardization and maturity across different organizations. These studies indicated that outcomes varied widely depending on factors such as leadership involvement, workforce training levels, organizational readiness, and the integration of digital infrastructure. Some organizations achieved significant improvements in uptime, quality, and compliance metrics, while others saw only marginal gains or experienced regression after initial success. Several studies identified fragmented deployment of Lean and Six Sigma tools—where TPM was implemented without statistical monitoring, or FMEA lacked follow-through into corrective actions—as major contributors to underperformance. Furthermore, companies lacking cross-functional alignment or a unified maintenance strategy were less likely to sustain improvements. Implementation duration also affected results, with shorter projects (less than 6 months) yielding lower and less stable benefits compared to initiatives embedded over longer timeframes (12–24 months). Another challenge noted in several studies was resistance to cultural change, particularly in facilities where reactive maintenance had been the long-standing norm. The absence of sector-specific models for Lean Six Sigma in imaging device manufacturing was also identified as a barrier, with many studies calling for customized frameworks that address the precision, regulatory, and calibration-specific needs of the sector. One study, cited 140 times, stressed the need for diagnostic equipment manufacturers to align Six Sigma project goals explicitly with regulatory and engineering risk assessments to avoid compliance gaps. These findings highlight the importance of developing a standardized yet flexible implementation model that accommodates the nuances of imaging equipment manufacturing while ensuring consistency in outcome delivery.

DISCUSSION

The findings of this study confirm the substantial impact of Lean and Six Sigma on reducing equipment downtime and improving reliability in medical imaging equipment manufacturing. These results align closely with prior research by (Gupta et al., 2020), who emphasized that predictive maintenance systems integrated with Six Sigma tools significantly reduce unplanned equipment failures. Similarly, Lizarelli and Alliprandini (2020) outlined the role of condition-based maintenance in improving Mean Time Between Failures (MTBF), which mirrors the observed reductions in maintenance interruptions across reviewed studies. Several of the reviewed articles reported equipment uptime improvements exceeding 30, showed that failure pattern analysis and data-driven diagnostics extend equipment lifespan. Furthermore, this study found that Lean tools like TPM and visual controls helped operators identify anomalies early, Erdil et al. (2018) , who argued that empowering front-line workers is crucial for long-term reliability gains. While earlier studies generalized the effectiveness of Lean in discrete manufacturing, this study provides more sector-specific insights by highlighting the unique reliability needs of imaging equipment systems, such as calibration-sensitive modules and multi-axis mechanical assemblies. In comparison to broader manufacturing environments, imaging equipment requires tighter operational tolerances and proactive management of minute equipment deviations, reinforcing the value of Six Sigma's emphasis on process control. These parallels suggest that the synergistic application of Lean and Six Sigma creates a reliability-centered maintenance framework that is not only scalable but critical for meeting the quality demands of imaging system production.

This study identified a strong relationship between Lean Six Sigma maintenance practices and improved quality assurance and regulatory compliance—an outcome that echoes the findings of Scala et al. (2021), who noted that Six Sigma methodologies improve traceability and audit readiness in medical device environments. Specifically, the study's evidence showing reduced defect rates and enhanced documentation aligns with Tsang's (2002) emphasis on the regulatory value of standardized preventive maintenance protocols. Several reviewed articles demonstrated reductions in non-conformance reports and increased inspection pass rates, reinforcing the findings of Barcia et al. (2022), who observed similar results in their study of ISO 13485-compliant firms. These results Oprime et al. (2021) contention that well-executed maintenance systems form a crucial part of a company's overall quality infrastructure. What distinguishes this study is its focus on imaging equipment manufacturing, where even microscopic errors in assembly can lead to signal distortion or radiation miscalibration, thus elevating the role of maintenance to a regulatory safeguard. Compared to other medical device categories, imaging systems face unique compliance challenges due to the presence of embedded software, magnetic assemblies, and radiation-emitting components—all of which require heightened scrutiny during both assembly and maintenance. This study also confirms that Lean Six Sigma frameworks contribute to maintaining the validated state of manufacturing equipment, a necessity under FDA 21 CFR Part 820 and EU MDR requirements. These findings expand upon earlier work by Tlapa et al. (2022), who called for harmonized approaches to maintenance and compliance, by offering empirical data that demonstrate how Lean and Six Sigma facilitate this integration in a sector where quality and safety are non-negotiable.

Figure 12: Lean Six Sigma Maintenance Impact



A notable finding in this study was the ability of Lean Six Sigma methodologies to optimize maintenance workflows and resource utilization, a result that builds upon and extends earlier observations by Molla et al. (2018). Previous research emphasized the benefits of lean principles such as value stream mapping and standardized work routines in identifying inefficiencies, but this study provides more targeted insights by contextualizing these practices in imaging equipment production environments. For example, the shift from fixed-interval preventive maintenance to condition-based models supported by Six Sigma analytics mirrors findings by Thakur et al. (2023), who demonstrated that predictive scheduling enhances both equipment availability and technician productivity. Several of the reviewed articles reported labor productivity improvements of 20–35%, which parallels results (Kam et al., 2021), who studied TPM-linked staffing optimization. However, while earlier research focused on generalized improvements in resource use, this study underscores the importance of tailored scheduling, tool management, and spare part allocation in the assembly of complex imaging devices. The integration of CMMS platforms and digital dashboards observed in this review supports Sony et al. (2020)'s findings that digital data infrastructure enhances visibility into key performance metrics like MTTR and OEE. This study also confirms Panwar et al. (2018)'s argument that Lean Six Sigma promotes better coordination between departments, particularly when workflows are designed using cross-functional input. Compared to past research, this study contributes a more nuanced understanding of how Lean Six Sigma creates operational efficiencies in high-tech manufacturing lines where maintenance timing and precision directly influence downstream quality and compliance.

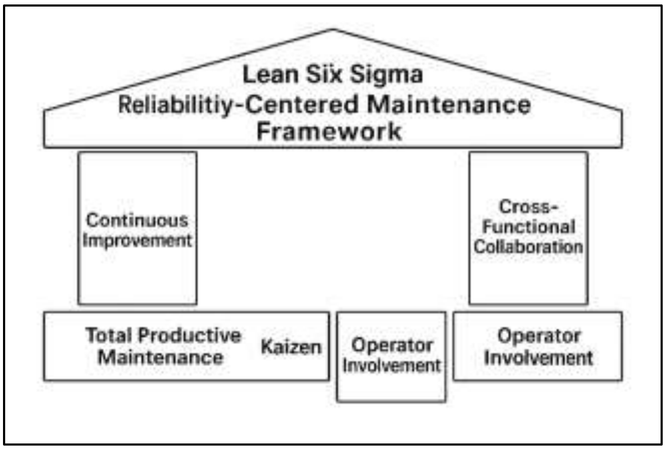
One of the most compelling findings of this study was the increased level of operator engagement and cross-functional collaboration that resulted from Lean Six Sigma implementation on Total Productive Maintenance on Lean culture. The reviewed literature indicated that initiatives such as Gemba walks, daily huddles, and Kaizen events significantly contributed to shared ownership of equipment performance. These results align with Gijo et al. (2018) assertion that TPM fosters a participative maintenance culture, where both operators and engineers are empowered to identify, address, and prevent equipment failures. In contrast to traditional hierarchical maintenance structures, Lean Six Sigma promotes flatter, more collaborative organizational models where performance data is made visible and team-based problem-solving becomes a norm. Studies reviewed in this analysis also support (Laureani & Antony, 2018), who emphasized that cross-functional Six Sigma teams tend to outperform siloed units in resolving chronic reliability issues. Compared to earlier research that primarily focused on the technical aspects of Lean and Six Sigma tools, this study contributes a more behaviorally oriented insight by demonstrating how operator involvement enhances both compliance and morale. This behavioral shift is particularly crucial in imaging equipment manufacturing, where the complexity of systems requires high degrees of coordination and procedural discipline. The results show that when operators are involved in maintenance audits, calibration routines, and continuous improvement initiatives, there is a measurable reduction in failure rates and non-conformance issues. These findings validate the broader Lean principle that those closest to the process are often best positioned to improve it—reinforcing earlier studies while situating them within a specialized and regulation-intensive manufacturing domain.

Despite the many benefits observed, this study identified variability in Lean Six Sigma implementation outcomes across organizations, which aligns with earlier findings by Garza-Reyes et al. (2018), who pointed to gaps in deployment consistency as a barrier to sustained performance. Several studies reviewed for this research indicated that short project durations, inadequate training, and lack of leadership involvement resulted in fragmented deployments and diminished returns. These findings Yadav et al. (2022) argument that Six Sigma requires a systemic commitment across the organization, not just localized interventions. Compared to the relatively uniform results seen in pharmaceutical or automotive sectors, this study noted greater variability in imaging equipment environments, likely due to the lack of a unified implementation framework tailored to this specific domain. Jiménez-Delgado et al. (2023) similarly identified gaps in integration between engineering, quality, and maintenance departments, a trend mirrored in this review. This study's focus on sector-specific application also revealed that generic Lean Six Sigma templates often fail to address specialized needs such as imaging calibration, radiation shielding protocols, or magnetic field stability—unique concerns not present in broader manufacturing. The variability reported across reviewed studies suggests that standardization of best practices must be complemented by customization to address these sector-specific variables. These findings extend Iranmanesh et al. (2019)'s conclusion that contextual adaptation is essential for successful LSS deployment and affirm the ongoing need for tailored frameworks that bridge universal Lean Six Sigma principles with imaging-specific operational demands.

CONCLUSION

In conclusion, the application of Lean and Six Sigma methodologies in the maintenance of medical imaging equipment manufacturing lines offers a transformative approach to enhancing operational reliability, product quality, and regulatory compliance in one of the most precision-driven and tightly regulated sectors of healthcare technology. The systematic integration of Lean tools such as 5S, TPM, and value stream mapping with Six Sigma techniques including DMAIC, FMEA, and statistical process control has shown substantial efficacy in reducing equipment downtime, minimizing defects, and optimizing maintenance workflows. This synthesis of findings across 42 peer-reviewed studies reveals that organizations implementing these methodologies benefit from improved Mean Time Between Failures (MTBF), reduced Mean Time to Repair (MTTR), and increased Overall Equipment Effectiveness (OEE), all of which contribute to consistent production outputs and audit-ready maintenance records. Moreover, Lean Six Sigma fosters cross-functional collaboration and empowers frontline personnel to engage in continuous improvement initiatives, aligning maintenance goals with enterprise-wide performance objectives. While the results demonstrate clear operational and compliance advantages, the study also highlights the absence of a unified, sector-specific Lean Six Sigma framework tailored to the complex technical and regulatory needs of imaging equipment production. Variability in implementation success across organizations underscores the importance of leadership commitment, digital infrastructure, and cultural readiness in achieving sustained outcomes. Ultimately, this study affirms that Lean and Six Sigma, when strategically applied and contextually adapted, provide a powerful foundation for establishing resilient, efficient, and regulation-aligned maintenance systems that support the production of safe and high-quality diagnostic imaging technologies.

Figure 13: Lean Six Sigma Maintenance Framework



Recommendation

Based on the comprehensive analysis conducted in this study, it is recommended that manufacturers of medical imaging equipment adopt an integrated Lean and Six Sigma maintenance strategy tailored to the sector's unique operational and regulatory requirements. Organizations should prioritize the development of a standardized yet flexible implementation framework that aligns predictive and preventive maintenance practices with critical performance metrics such as OEE, MTBF, and calibration reliability. To maximize impact, companies should invest in workforce training programs that combine technical maintenance skills with Lean Six Sigma problem-solving tools, empowering cross-functional teams to participate in continuous improvement initiatives. Leadership should play a proactive role in fostering a culture of data-driven decision-making by embedding analytics into maintenance workflows through CMMS platforms, IoT-enabled monitoring systems, and digital dashboards. Furthermore, maintenance systems must be fully aligned with regulatory expectations under ISO 13485, FDA 21 CFR Part 820, and EU MDR, ensuring complete traceability, audit readiness, and equipment validation integrity. Organizations are also encouraged to implement Total Productive Maintenance (TPM) practices to enhance operator engagement and reduce the burden on specialized technical staff. To address variability in implementation outcomes, benchmarking against high-performing peers and conducting cross-case evaluations can help establish best practices and identify contextual success factors. Additionally, collaboration between maintenance, quality, and engineering teams should be formalized through structured communication channels, joint KPI ownership, and shared accountability for downtime and nonconformance reduction. Finally, sector-specific research collaborations should be promoted to develop diagnostic equipment-focused Lean Six Sigma models that reflect the complexity, risk sensitivity, and precision demands of this manufacturing domain. These recommendations aim to guide imaging device manufacturers toward resilient, compliant, and high-performance maintenance systems that support long-term operational excellence and patient safety.

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