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Lean Six Sigma and AI in MedTech Quality Assurance

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Published by IntuitionLabs · 2026-02-27 · lean six sigma · artificial intelligence · medtech quality · iso 13485 · dmaic framework · machine learning · medical device qms · quality assurance · predictive analytics · fda compliance

Original article: <https://intuitionlabs.ai/articles/lean-six-sigma-ai-medtech-quality-systems>



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Executive Summary

Lean Six Sigma (LSS) and artificial intelligence (AI) offer complementary approaches to examine in MedTech quality systems. LSS combines Lean's emphasis on waste elimination with Six Sigma's emphasis on process capability and variation reduction ([ASQ](#)). Meanwhile, AI techniques (machine learning, computer vision, natural language processing, etc.) are increasingly applied to manufacturing and quality assurance, offering real-time monitoring, predictive analytics, and automation of complex analysis. Experts argue that LSS and AI are *synergistic*: LSS stabilizes processes and ensures high-quality data, de-risking AI deployment, while AI accelerates LSS by automating data analysis and enabling continuous, predictive improvement ([www.linkedin.com](#)) ([opex90.com](#)). In MedTech, where stringent regulatory standards (e.g. ISO 13485, FDA's [Quality Management System Regulation \(QMSR\)](#)) demand robust [quality management systems](#), evaluate LSS and AI against applicable quality requirements and the intended use of each tool.

This report examines Lean Six Sigma and AI within medical device quality systems, including DMAIC, inspection, [eQMS](#), predictive analytics, data governance, and human oversight. [ASQ](#) describes establishing a trustworthy baseline as part of DMAIC's Measure phase ([ASQ](#)). Use that baseline to evaluate a proposed AI application.

The discussion distinguishes expert commentary, a company-authored process-development account, and an explicitly hypothetical implant scenario. The scenario's figures are assumed. Do not interpret candidate applications or commentary as evidence that combining LSS and AI generally outperforms either approach alone.

Introduction and Background

Medical technology (MedTech) quality systems encompass the processes and controls used by device and diagnostic manufacturers — as well as healthcare providers — to ensure product safety, efficacy, and regulatory compliance. Under applicable quality and regulatory frameworks (ISO 13485:2016 for QMS, FDA 21 CFR Part 820, EU MDR, etc.), organizations must rigorously manage design, production, and [post-market surveillance](#), and continuously improve their processes ([www.hardianhealth.com](#)) ([www.hardianhealth.com](#)).

FDA's Quality Management System Regulation took effect on February 2, 2026 ([FDA](#)). Lean Six Sigma (LSS) methodologies have been widely adopted in manufacturing to drive such continuous improvement: Lean originally emerged from Toyota's waste-elimination techniques, while Six Sigma (popularized by Motorola and GE) emphasizes reducing process variation and defects (to ~3.4 defects per million opportunities) ([www.advantmedical.com](#)) ([www.advantmedical.com](#)). Modern MedTech operations often incorporate LSS principles to eliminate inefficiencies and improve quality (e.g. applying value-stream mapping, 5S, FMEA, statistical process control, etc.) ([www.advantmedical.com](#)) ([www.advantmedical.com](#)).

In parallel, artificial intelligence (AI) has matured into practical tools for industrial and healthcare applications. AI techniques include machine learning (ML), deep learning, computer vision, and natural language processing (NLP), which can analyze large datasets and automate complex tasks. In MedTech, AI is already present in devices (e.g. imaging AI tools) and backend systems (e.g. digital pathology analysis). Now, AI is being applied in quality systems: for example, AI-powered computer-vision inspection can detect microscopic defects in molding or printed circuit boards, and ML algorithms can predict equipment maintenance needs before breakdown. Unlike LSS's structured project methodology, AI offers continuous, data-driven automation.

The convergence of LSS and AI is thus a natural evolution. Both rely on data-driven decision-making. A recent analysis notes that LSS lays the “essential foundational work — stabilizing processes, ensuring [data quality](#), and reducing variation — that de-risks AI initiatives” ([www.linkedin.com](#)). Conversely, AI tools “supercharge each phase of the traditional LSS DMAIC framework”: NLP can automate customer feedback analysis in the Define phase, IoT sensors and vision systems can automate data collection in Measure, ML finds complex root causes in Analyze, digital twins simulate solutions in Improve, and predictive analytics turns Control charts into proactive alerts ([www.linkedin.com](#)). Measurement systems still need evaluation, maintenance, and improvement ([ASQ conference abstract](#)). In other words, LSS provides the stable, high-quality data environment which AI needs, while AI turns LSS from periodic projects into a continuous, enterprise-wide improvement engine ([www.linkedin.com](#)).

This report delves into how LSS and AI intersect in MedTech quality systems. We first review Lean and Six Sigma fundamentals and MedTech quality regulations (emphasizing ISO 13485 and FDA requirements). We then explore AI technologies relevant to manufacturing quality (machine vision, predictive analytics, etc.) and how they enhance LSS tools. Subsequent sections distinguish reported process development, proposed AI applications, and an illustrative scenario. Throughout, we distinguish primary regulatory sources from industry commentary. The goal is a comprehensive, scholarly treatment of the past, present, and future of Lean Six Sigma meeting AI in MedTech quality systems.

Lean Six Sigma: Principles and Practice in MedTech

Lean manufacturing, originally from Toyota Production System, is built on eliminating the “seven wastes” (overproduction, waiting, transport, extra inventory, motion, over-processing, defects) to streamline value flow ([www.advantmedical.com](#)). Six Sigma, developed by Motorola in the 1980s, uses statistical methods (DMAIC: Define, Measure, Analyze, Improve, Control) to reduce process variation to near-perfect levels ([www.advantmedical.com](#)) ([www.advantmedical.com](#)). Lean Six Sigma (LSS) is the synergistic integration of both approaches, using Lean's waste-removal and Six Sigma's data-driven rigor. According to industry definitions (ASQ), Six Sigma is “a method...to improve the capability of [business] processes...increase in

performance and decrease in...variation...leads to defect reduction and improvement in...quality of products or services” (www.advantmedical.com). Advant Medical (an Irish contract manufacturer) emphasizes that at their facility, “Six Sigma is one of the methods we use to nurture a Lean philosophy...maximise efficiencies, eliminate waste and streamline business processes” (www.advantmedical.com). In effect, Lean removes non-value activities and variability, while Six Sigma uses tools like Control Charts, FMEA (Failure Mode and Effects Analysis), Gage R&R, and hypothesis testing to quantify and eliminate defects (www.advantmedical.com) (www.advantmedical.com).

In a company-authored account published on May 1, 2025, Pelham Plastics described its revised urinary placement catheter tip process as still undergoing testing, with samples meeting dimensional and cosmetic requirements ([Kevin Crowell, Pelham Plastics](#)). Treat this as a process-development account, rather than completed production evidence or a study of AI.

Key LSS tools in the MedTech context include **Value Stream Mapping (VSM)** (documenting all steps from design input to final product to find waste), **Kaizen/Poka-Yoke** (continuous improvement events and error-proofing fixtures), **5S/Visual Workplace** (organizing workstations for efficiency), and **Statistical Process Control (SPC)** charts (monitoring key measures against control limits) (www.advantmedical.com) (www.advantmedical.com). The QMSR incorporates ISO 13485:2016 by reference ([FDA final rule](#)). ISO describes the standard as helping manufacturers meet regulatory requirements and manage risk ([ISO](#)). For current CAPA and risk controls, apply the incorporated standard and the applicable FDA provisions; do not use a universal quality percentage as an acceptance criterion. Historically, former 21 CFR 820.100 required manufacturers to establish and maintain CAPA procedures ([2025 CFR](#)).

Thus, LSS in MedTech often yields both cost and quality benefits. By focusing on process stability and waste, companies decrease scrap, avoid recalls, and shorten time-to-market while satisfying regulatory “Continuous Improvement” clauses (www.hardianhealth.com). However, LSS relies on human teams collecting and analyzing data, which may be slow or limited by dataset size. This is where AI technologies now promise to extend LSS’s reach and speed possible gains.

AI Technologies in Quality Management

AI encompasses a spectrum of computational techniques that allow systems to learn from data, recognize patterns, and make predictions. In the context of MedTech quality systems, **machine learning (ML)** algorithms can find non-obvious correlations in manufacturing data; **digital computer vision** can replace manual inspection; **predictive analytics** (a form of AI) can forecast equipment failures or quality drifts; and **natural language processing (NLP)** can analyze unstructured records (e.g. complaint narratives) for emerging trends. Today’s AI software often combines these: e.g. deep convolutional neural networks (CNNs) for image analysis, recurrent neural networks (RNNs) or large language models for text, and ensemble methods for risk scoring.

Candidate applications include **non-destructive testing (NDT)** with camera inspection and predictive maintenance using equipment data. Evaluate these applications with representative data and documented limitations rather than assuming inspection speeds or defect reductions.

FDA describes its Software Precertification (Pre-Cert) program as a completed pilot (FDA). Do not treat it as a current manufacturing-AI compliance pathway.

Define each AI tool's intended use, retain human review of quality decisions, and evaluate its performance within the QMS before scaling deployment. The discussion below presents possible ways to combine such tools with DMAIC, without adoption forecasts or unverified comparative figures.

Lean Six Sigma Meets AI: Synergy and Implementation

At the core of LSS–AI integration is the idea that AI amplifies Lean and Six Sigma practices, while LSS provides the stable environment AI needs. As Anton Dubov (2025) summarizes: *“LSS provides the essential foundational work — stabilizing processes, ensuring data quality, and reducing systemic variation — that de-risks AI initiatives... In turn, AI accelerates and elevates LSS, transforming it from a periodic, project-based methodology into a continuous, predictive engine for enterprise-wide improvement.”* (www.linkedin.com). This synergy manifests at each DMAIC phase:

- **Define Phase:** Traditionally, teams gather Voice of Customer (VOC) and project charters. AI (e.g. NLP sentiment analysis) can automatically mine patient feedback, social media, and complaint logs to quantify customer needs or priority issues. Dubov notes that AI “automates customer feedback analysis” in the Define phase (www.linkedin.com).
- **Measure Phase:** Lean/Six Sigma measurement often uses manual data collection and SPC. With AI/IoT, high-frequency sensors on the line collect detailed process parameters (temperature, torque, vision images) in real time. Computer vision can automate measurements of fill levels, alignment, or surface quality (www.linkedin.com). For example, an AI camera system can count particulate contamination on a sterile device surface in real time, feeding immediate metrics into control charts. Study measurement variation before relying on these measurements (ASQ).
- **Analyze Phase:** This is a classic Six Sigma function (statistical analysis, fishbone diagrams). AI introduces advanced analytics: machine learning algorithms can ingest multivariate process data and identify complex nonlinear relationships or subtle drift trends invisible to simple SPC. As Dubov points out, ML “uncovers complex root causes...in the Analyze phase” that traditional methods miss (www.linkedin.com). Indeed, an ML model trained on years of defect and environmental data might reveal that slight changes in raw material viscosity, combined with ambient humidity, predict a certain defect spike. This insight can come far faster than weeks of statistical hypothesis tests.
- **Improve Phase:** Lean/Kanban or Kaizen initiatives propose fixes. Here, **digital twins** — AI-driven virtual simulations of the production line — allow teams to test process changes safely. Dubov notes digital twins enable “risk-free simulation of solutions in the Improve phase” (www.linkedin.com). For example, before installing a new assembly robot, an AI twin simulates thousands of parts to optimize grip motion parameters. Additionally, optimization algorithms (such as genetic algorithms or reinforcement learning) can determine the best settings (e.g. optimal conveyor speed and worker-infeed coordination) to maximize throughput.
- **Control Phase:** Typically control means SPC charts and periodic audits. AI transforms this into proactive control: predictive analytics continuously monitors key metrics and flags anomalies in advance. Instead of reacting to an out-of-control point on a chart, the system alerts staff hours earlier if

trends indicate a process is drifting. Dubov states predictive analytics “transforms the Control phase from a reactive to a proactive function” (www.linkedin.com).

The synergy is not merely theoretical. Dan Tompkins (OpEx90) describes how practitioners merge LSS expertise with AI: “AI-driven tools are enabling specialists to proactively identify and address quality issues before they escalate, shifting from firefighting to strategic prevention... AI’s predictive analytics harmonize with Lean Six Sigma methodologies, empowering practitioners... to deliver sharper insights” (opex90.com). In practice, quality engineers at a medical device firm might use an AI dashboard that alerts them to emerging patterns (e.g., a cluster of micro-defects) which then becomes the focus of a Kaizen/5Y root-cause analysis. This closed loop — AI finds anomalies, LSS methods implement fixes, and AI verifies the improvement — creates what Dubov calls an “LSS+AI Continuous Improvement Loop” (www.linkedin.com).

Table 1 compares the typical functions of Lean/Six Sigma vs AI in quality applications:

DMAIC Phase / Aspect	Traditional Lean Six Sigma Tools	AI-Driven Techniques & Benefits
Define (Goal Setting)	Voice of Customer interviews, SIPOC diagrams, prioritization matrices.	NLP and text mining automate analysis of complaint narratives, patient surveys, even literature (ISO14971 vigilance) to quantify issues (www.linkedin.com). AI can rapidly categorize large feedback datasets.
Measure (Data Collection)	Manual data logs, gauges, SPC charting, operator reports.	IoT sensors and high-resolution cameras can provide continuous measurements. Validate and improve the measurement system as required. Evaluate computer vision against the inspection requirements. Data lakes integrate diverse sources for analytics. (ASQ).
Analyze (Root Cause)	Statistical tests, Pareto analysis, fishbone diagrams, design FMEAs.	Machine learning (clustering, regression, classification) sifts through big data to reveal hidden patterns. For example, ML can analyze past CAPA reports to predict underlying cause categories (www.linkedin.com).
Improve (Implementation)	Kaizen/5S events, process rebalancing, pilot studies, design verification.	Digital twins allow simulation of process tweaks. AI optimization algorithms automatically search for ideal process parameters and spacing. Changes can be validated via rapid virtual trials.
Control (Sustainability)	Control charts, MSA studies, audits, standard work documentation.	Predictive analytics monitor metrics to preempt drift. AI-driven control feedback loops adjust process parameters in real-time (model predictive control). Continuous surveillance (e.g. real-time SPC) is automated.

In sum, AI “powers” each stage of DMAIC, making LSS faster and deeper (www.linkedin.com) (opex90.com).

Table 2 below illustrates in more conceptual terms how Lean Six Sigma and AI compare as complementary approaches:

Aspect	Lean Six Sigma (LSS)	Artificial Intelligence (AI)	LSS + AI Synergy
Core Focus	Eliminate waste, reduce variation via structured improvement projects (www.advantmedical.com) (www.advantmedical.com)	Data-driven prediction, pattern recognition, automation of analysis tasks	Data-driven continuous improvement: stable base allows AI optimization; AI-provided insights drive further LSS projects (www.linkedin.com)

Aspect	Lean Six Sigma (LSS)	Artificial Intelligence (AI)	LSS + AI Synergy
Data Handling	Periodic data gathering and statistical analysis (small/clean datasets)	Big data ingestion, real-time sensor streams, unstructured text/images	AI enhances data analysis in LSS: ML models handle larger, complex datasets for SPC and root cause, while LSS ensures data validity (proper 5S, calibration)
Decision Process	Human-led workshops (DMAIC teams) make decisions based on charts and consensus	Automated model outputs (classifications, anomaly scores) provide insights	AI suggests actionable findings (e.g. probable cause), but human experts validate and decide fixes (human-in-the-loop for quality risk) (www.linkedin.com)
Speed & Scale	Improvement projects can take weeks/months; limited scope per project	Continuous monitoring & instant alerts across entire facility; scalable to many lines	Rapid identification of issues across operations; LSS teams focus on highest-impact areas flagged by AI, accelerating ROI
Illustrative Tasks	Use DMAIC to investigate defects and improve a process.	Evaluate a model for inspection or equipment monitoring.	Verify measurement-system effectiveness before interpreting process capability (ASQ event description); use human review to assess suggested process changes.

These tables illustrate the *complementarity*: Lean Six Sigma’s structured methodology provides the disciplined framework and cultural foundation, while AI supplies a new level of analytical horsepower and automation. Crucially, both are data-centric. As Dubov notes, their common commitment to “data-driven decision-making” naturally connects them (www.linkedin.com).

Evidence Limits and Candidate QMS Applications

Sajjad Mansoor’s author commentary describes AI as potentially valuable when governed within the QMS ([original post](#)). Treat the following as candidate workflows to evaluate, rather than implementation results:

- *Complaint handling*: Evaluate AI-assisted classification and prioritization of reports, with human review retained.
- *CAPA analytics*: Explore historical CAPA, nonconformance, and audit records for recurring failure modes; retain quality judgment.
- *Supplier monitoring*: Assess supplier performance, delivery deviations, and quality metrics as possible inputs to risk review.
- *Post-market surveillance*: Consider NLP-assisted review of complaints, service reports, and literature for safety trends.

Define intended use and limitations, document validation and human oversight, and integrate changes into procedures and training. Do not attach percentages, earlier-detection timelines, or a history of carefully governed deployments to this qualitative commentary.

Before claiming a benefit from an LSS–AI project, specify the baseline, evaluation period, sample size, defect definition, and comparison method. Distinguish modeled benefits from attained outcomes, and evaluate the contribution of LSS, AI, and other process changes separately. Plausible complementarity is a rationale for

evaluation, rather than proof of general superiority.

Illustrative Scenario: AI-Driven Quality in a Medical Device Firm

Hypothetical example: All organizations, events, and figures in this scenario are assumed for illustration; they are not measured results or empirical evidence. A mid-sized orthopedic implant manufacturer struggled with inconsistent device coatings (suture attachments) causing rejection of 8% of products. They launched a Lean Six Sigma project: teams mapped the coating line (5S, VSM) and identified excess variability in curing ovens. First, they applied Six Sigma tools: they measured oven temperature profiles, devised standard operating procedures, and trained operators (closing process capability gap from Cpk 1.2 to 1.5). Defects dropped to 4%.

To go further, the company integrated AI: they installed high-resolution cameras to capture each implant's coating as it exited curing. A computer vision model (trained on images of good vs bad coatings) automatically detected 98.5% of defectively coated implants, up from 85% by the human eye. This real-time output fed back into the process data: an ML algorithm correlated subtle oven temperature drifts and adhesive viscosity changes with the vision-reported defects. It identified a recurring pattern (humidity spikes caused partial cure defects) that had eluded manual analysis. Engineers then added humidity control and slight timing adjustments.

The result: defective products fell to **1.0%**. Cycle time improved by 15% (less rework/polish cycles) and scrap costs dropped by 75%. Moreover, the quality team was now alerted instantly by the AI system if defect occurrences began rising, allowing immediate intervention. In effect, Lean Six Sigma had stabilized the process, and AI had optimized it further and provided continuous control—an illustration of the LSS+AI feedback loop described by Dubov (www.linkedin.com) (www.linkedin.com).

Discussion: Implications and Future Directions

The integration of Lean Six Sigma and AI raises practical questions for quality teams. NIST recommends human judgment when selecting AI trustworthiness metrics and their thresholds ([NIST AI RMF 1.0](#)):

- **Manufacturing Efficiency and Cost:** ASQ recommends establishing baseline values for quality and productivity and tracking improvement ([ASQ](#)). Treat improved OEE (overall equipment effectiveness), yield, and cost from a combined LSS–AI project as possibilities to evaluate. Compare rework, inventory, downtime, and release-cycle metrics against a documented project-specific baseline. Before claiming that the combination outperforms LSS or AI alone, specify the evaluation period, sample size, and comparison method, and assess the contribution of each approach and other process changes; do not assume a standard improvement percentage.
- **Regulatory Compliance:** Consult FDA's [QMSR resources](#) for applicable quality-system obligations. Assess proposed AI tools against their intended use, document human review and change control, and obtain evidence before treating an output as suitable for a quality decision. Do not infer compliance from an AI feature or apply device-product AI standards automatically to manufacturing software.

- **Organizational Change Management:** Overcoming cultural hurdles is critical. Lean Six Sigma already requires cross-functional teams and a data-driven mindset. Adding AI requires new skills (data science, machine learning) and new trust in “algorithmic outputs.” To blend them, companies must either hire data analysts into quality teams or upskill engineers. Early adopters report that establishing “*AI Champions*” within quality departments, who speak both quality and data science, is effective. Moreover, maintaining human oversight is crucial: AI should assist, not replace, GMP-trained personnel (www.linkedin.com).
- **Data Infrastructure and Quality:** LSS often exposes the need for good data (if operators found inconsistent logging practices, data cleaning became a Lean project first). AI raises that bar by requiring large, high-integrity datasets. Successful projects start with “Lean data management”: eliminating duplicate records, ensuring traceability. Many firms harden their LSS foundations (standardized data collection, CMMS integration) before layering AI.
- **Technology and Vendor Ecosystem:** Evaluate quality-software and inspection vendors against defined requirements. Request evidence for the proposed workflow, data handling, validation support, and human review; distinguish product labels from demonstrated process improvements.
- **Patient Impact and Public Health:** Perhaps the largest impact is on patients. More reliable devices and faster innovation cycles improve patient safety and outcomes. For example, reducing device defects by even a few percentage points can avoid adverse events (e.g. a defective stent or implant fixation can cause serious harm). AI-driven post-market surveillance (scanning literature and social media) could catch rare risks earlier, contributing to public health. On the other hand, widespread AI also raises ethical questions (data privacy, AI biases) even in manufacturing contexts. Companies must ensure patient data used for AI models (e.g. in post-market vigilance) are de-identified and secured (www.linkedin.com).
- **Future Directions:** Looking ahead, several trends are anticipated. **Digital Twins and Augmented Factories:** Efforts are underway to create end-to-end digital twins of production lines. Combining LSS’s process maps with AI-driven simulation, manufacturers hope to run continuous virtual experiments on their actual factory, further reducing downtime. **Generative AI:** Large language models may soon assist in drafting CAPA reports or summarizing root causes, accelerating LSS documentation. **Adaptive Learning Control:** Some envision feedback loops where ML models automatically fine-tune process controls (e.g. adjusting flow rates on-the-fly) under human supervision, effectively pushing LSS control charts into autonomous mode. **Supply Chain Resilience:** AI integrated with LSS could optimize inventory (Lean pull systems) by predicting shortages or delays; this was glimpsed during COVID-19 disruptions. **RegTech and Audit:** AI may also audit LSS projects themselves (e.g. text-mining audit reports for common improvement threads, or using anomaly detection to spot compliance issues in vendor data) – essentially using AI to ensure the **quality of the quality system**.

However, challenges remain. Data silos, legacy equipment, and limited budgets can slow adoption. Also, as Mansoor cautions, “*deploying AI faster than procedures, controls, and training can support*” will backfire (www.linkedin.com). Therefore, a phased approach is advised: start with augmenting LSS phases with AI (as tools, not replacements) and ensure robust governance. Firms should pilot small, demonstrate ROI, and then scale.

Conclusion

Lean Six Sigma offers a structured approach to process improvement, while AI offers tools for analysis and monitoring. Evaluate their combination against the specific quality problem, the baseline, and the applicable QMS requirements. Expert commentary and an assumed scenario should not be used to promise superior outcomes, guaranteed accuracy, or regulatory acceptance.

NIST's AI RMF 1.0 recommends testing AI systems before deployment and regularly during operation ([NIST](#)). For a MedTech quality application, define the intended use and test conditions; assess measurement performance, false-positive and false-negative rates, calibration, and drift ([NIST evaluation guidance](#)). Retain human oversight and document the evidence for any claimed improvement. The implant scenario illustrates a possible workflow; its assumed figures are not evidence of effectiveness.

References

Primary regulatory, standards, and measurement sources used for the repaired claims:

- [FDA: Quality Management System Regulation \(QMSR\)](#).
- [FDA: Quality Management System Regulation – Frequently Asked Questions](#).
- [FDA final rule: Medical Devices; Quality System Regulation Amendments \(89 FR 7496, February 2, 2024\)](#).
- [2025 CFR: Former 21 CFR 820.100, Corrective and preventive action](#).
- [ISO: ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes](#).
- [FDA: Digital Health Software Precertification \(Pre-Cert\) Pilot Program](#).
- [FDA: Computer Software Assurance for Production and Quality Management System Software \(final guidance, February 2026\)](#).
- [ASQ: DMAIC](#).
- [David J. Ingram and Wayne A. Taylor: Measurement System Analysis, ASQ conference abstract \(May 1998\)](#).
- [ASQ: Gage Repeatability and Reproducibility](#).
- [ASQ: Measurement System Analysis \(MSA\) and Process Capability \(Cpk\): Their Symbiotic Relationship \(September 17, 2024\)](#).
- [NIST AI RMF 1.0 \(2023\): AI Risks and Trustworthiness](#).
- [NIST AI RMF 1.0 \(2023\): AI RMF Core](#).
- [ASQ: Six Sigma](#).
- [Kevin Crowell, Pelham Plastics: Implementing Lean Six Sigma in the Medical Device Industry \(May 1, 2025\)](#).

FDA's February 2026 software-assurance guidance supersedes the September 24, 2025 guidance ([FDA](#)).

Industry commentary retained for context:

- [Sajjad Mansoor: AI in Medical Devices: Balancing Innovation and Compliance with FDA and ISO 13485 \(author commentary\)](#).

- Anton Dubov: The Perfect Symbiosis: How Lean Six Sigma Principles Supercharge AI Process Transformation (author commentary).
- OpEx90: AI Quality Control Revamps Lean Six Sigma (author commentary).
- Advant Medical: Six Sigma in Medical Device Manufacturing.

Use the commentary for ideas to evaluate. The company-authored Pelham account describes process development at its publication date. The implant scenario is an illustration with assumed figures.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://asq.org/quality-resources/six-sigma>
2. <https://www.linkedin.com/pulse/perfect-symbiosis-how-lean-six-sigma-principles-ai-process-dubov-t3nwc>
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