



AI-POWERED QUALITY: REDUCING THE COST OF POOR QUALITY IN MEDTECH

**HOW MEDTECH LEADERS ARE
USING AI TO IDENTIFY RISKS
SOONER AND PREVENT COSTLY
DOWNSTREAM FAILURES.**





Medical device manufacturers operate in one of the highest-stakes environments in the world. When a device fails in the field, the consequences extend far beyond warranty claims or production downtime. Patient safety is at risk. Regulatory scrutiny intensifies. Brand trust erodes. The financial impact of recalls, CAPAs, adverse-event reporting, and remediation can be severe.

According to the American Society of Quality (ASQ), quality-related costs can consume 15% to 20% of annual sales revenue in many organizations. Yet most quality issues don't originate on the shop floor. They begin much earlier in the design phase, when requirements are incomplete, risk controls are disconnected from product data, and traceability gaps go undetected until they surface during an audit or regulatory submission.

A new approach is necessary. By integrating artificial intelligence (AI) directly into core quality and engineering processes, manufacturers can prevent defects at the source, reduce downstream cost, and deliver safer innovations to patients faster.

This e-book explores how AI transforms MedTech quality management by enabling your organization to:

- **Prevent quality issues early** by identifying high-risk failure modes during design, before they propagate into manufacturing or the field
- **Reduce Cost of Poor Quality (CoPQ)** through simulation-driven design validation and AI-powered requirements quality
- **Ensure regulatory compliance** through automated, product-linked traceability aligned to FDA QMSR, ISO 13485, and EU MDR/IVDR
- **Build a closed-loop quality system** connecting R&D, manufacturing, and service across the full product lifecycle

The High Cost of Reactive Quality

Most MedTech manufacturers still manage quality reactively. Engineering, quality, and regulatory teams work in isolated systems without real-time visibility into shared product data. Design changes outpace documentation updates. Compliance records fall out of sync with product configurations. And when auditors or regulators come knocking, teams scramble to reconstruct traceability from fragmented sources.

This fragmentation has a compounding effect. A small traceability gap in early design becomes a nonconformance during manufacturing, a CAPA during regulatory review, and a potential service action for medical devices in-use in the field. Each stage of late discovery costs significantly more to resolve than if the issue had been identified at the source. And when it happens post-market, it impacts patients' access to care.

The regulatory environment is making this harder to ignore. FDA QMSR alignment with ISO 13485 increases expectations for systematic, traceable quality processes. The European Commission's MDR/IVDR simplification proposal reinforces the need for living documentation, lifecycle traceability, and continuous compliance, not static submissions. Industry research confirms the stakes: **organizations operating without a technology platform, or relying on paper-based systems, are consistently unable to close the quality loop.**

The organizations leading this shift are moving from paper to digital and from standalone, document-centric digital to a lifecycle-based, product-centric quality approach where quality events, compliance evidence, and corrective actions are always evaluated in the context of actual product data, configurations, and changes.



Quality Is an Investment. Failure Is a Cost.

$$\text{Total Cost of Quality} = \text{Cost of Good Quality} + \text{Cost of Poor Quality}$$

Cost of Good Quality (CoGQ): Prevention, validation, testing, and quality planning

Cost of Poor Quality (CoPQ): Scrap, rework, complaints, CAPAs, recalls, and adverse events

The goal isn't to spend less on quality, it's to spend more on preventing issues and less on correcting them.

A Digital Foundation Comes First

AI is not a replacement for strong quality processes. In MedTech, the greatest gains come when AI is built on a connected digital foundation that links product development, quality, regulatory, manufacturing, and service information across the lifecycle.

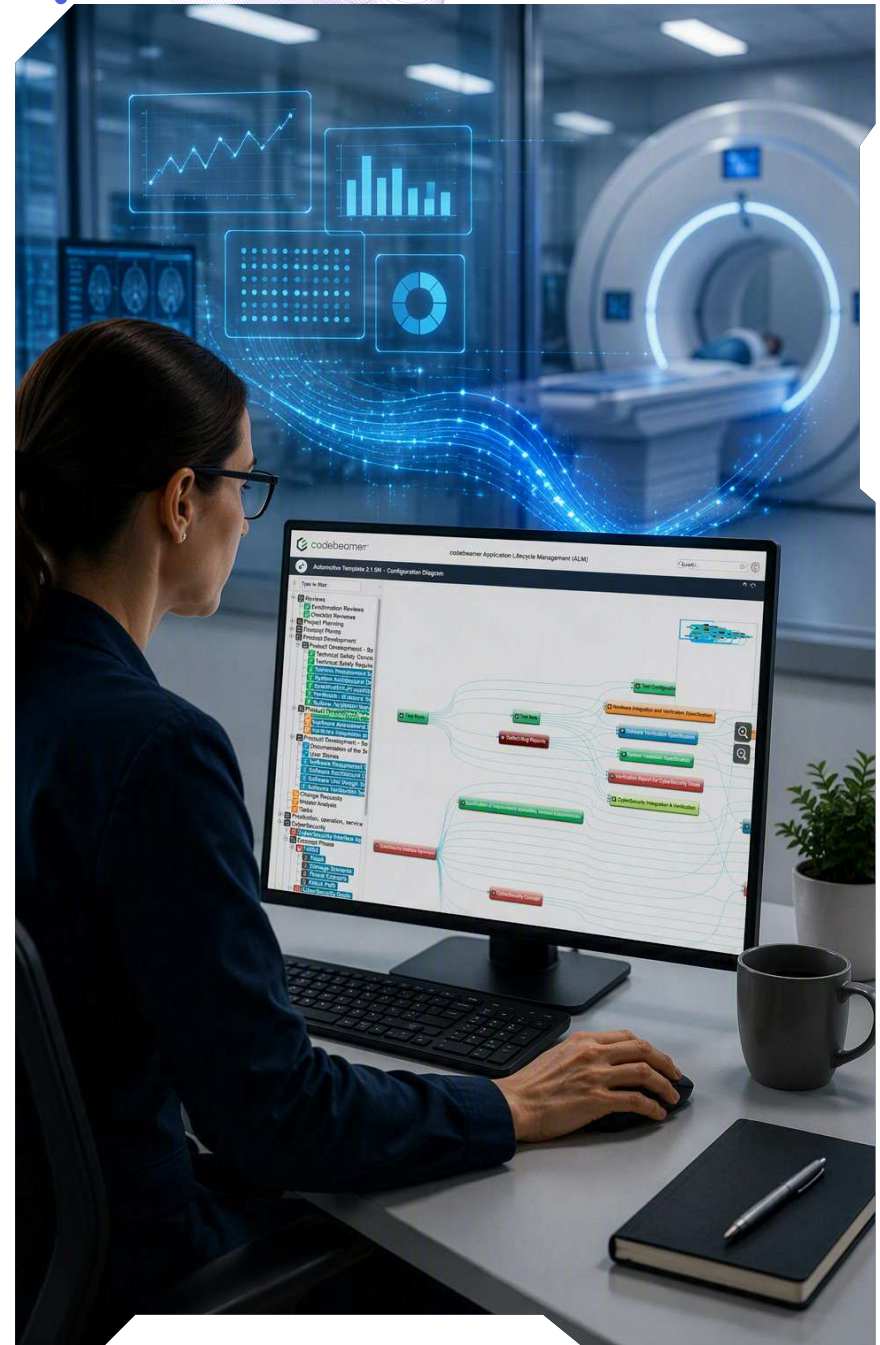
Modern lifecycle platforms help establish a single source of truth by connecting requirements, product data, risk, quality records, changes, and post-market information within a governed environment.

Only when this foundation is in place can AI reliably surface insights, identify risks, automate routine activities, and support informed decision-making with the full context regulators and auditors expect.

How AI Transforms MedTech Quality Management

Once a connected digital foundation is established, AI can accelerate and enhance the work already taking place across the product lifecycle. Rather than functioning as a standalone tool, AI delivers its greatest value when embedded directly into the systems used to manage the product lifecycle. In MedTech, this means deploying AI within governed, traceable systems where outputs remain explainable, auditable, and compliant by design.

Effective AI deployment in MedTech quality management operates across three core functions:



Advise: Turning Product Data into Instant Intelligence

AI agents act as an intelligent knowledge base, providing real-time access to critical product and quality information within the user's existing workflow. This eliminates the need for engineers and quality managers to search across siloed systems and ensures decisions are made with full product context.

For example, a quality engineer investigating a nonconformance can ask an AI assistant to surface all related complaints, associated product configurations, affected suppliers, and relevant FMEA entries instantly. Instead of spending hours reconstructing traceability, the team has the context needed to perform accurate root-cause analysis in minutes, reducing time-to-resolution and preventing recurrence.

Assist: Streamlining Complex Regulated Workflows

AI agents serve as intelligent partners that complete specific steps within larger quality and compliance processes. This reduces manual effort, minimizes human error, and frees skilled teams to focus on high-value problem-solving.

During a design review, an AI assistant can automatically cross-reference a new component against the bill of materials, flag potential conflicts with existing risk controls, and verify alignment with applicable regulatory requirements. This improves accuracy, accelerates review cycles, and ensures compliance without slowing the pace of development.

In requirements authoring, AI can flag ambiguous or incomplete requirements before they propagate into design, reducing downstream nonconformances, CAPAs, and audit findings.

Engineering teams using Codebeamer AI have reported up to 53% time savings in requirements creation and 40% faster test-case and specification development.

Automate: Executing Workflows with Minimal Human Intervention

At the most advanced level, AI agents execute entire workflows autonomously, connecting systems, monitoring data, and driving outcomes at a speed and scale that manual processes cannot match.

AI agents can automate portions of the engineering change management process, from analyzing change impact across the product structure to identifying affected stakeholders, documentation, requirements, and quality records. This reduces administrative burden and helps ensure every AI-supported action is traced and documented.

But in MedTech, automation must remain governed. Human-in-the-loop review is essential for verifying AI-generated outputs, assessing quality and regulatory implications, and approving final decisions. This balance allows organizations to accelerate routine workflows while maintaining the oversight, traceability, and audit readiness that regulated environments require.



Four Practical Steps for Implementation

Adopting AI for MedTech quality management is not a single event. It requires a disciplined, methodical approach that balances immediate operational gains with long-term regulatory defensibility. The following roadmap outlines the essential steps to incorporate AI effectively without compromising the data governance and traceability that regulators expect.

Step 1: Assess and Strengthen Your Data Foundation

AI is only as effective as the data it operates on. Before deploying advanced capabilities, you must ensure your product and quality data is accessible, structured, governed, and reliable. In many MedTech organizations, critical data remains trapped in siloed systems, spreadsheets, or paper-based records.

Audit your current data infrastructure. Map where your product data lives across engineering, quality, regulatory, and manufacturing functions. Identify disconnects between systems. Are your design history files (DHF) current and linked to product configurations? Is risk management data connected to verification and validation evidence?

Establish a single source of truth. Implement or optimize a PLM system that centralizes your product record and connects it to requirements, quality, and service data across the lifecycle. This digital foundation ensures issues are evaluated against the correct product context, including revisions, risk, change history, and field performance.

Contextualize your data for AI. Raw data needs governance and structure to be useful. Ensure that AI tools can understand the relationships between product elements, so that when the system identifies a “risk,” it distinguishes between a supply chain delay and a regulatory violation. A strong PLM foundation is what makes AI outputs defensible in a regulated environment.

Real-World Example: Building the Foundation Before AI

A global MedTech manufacturer seeking to accelerate and automate change control first focused on standardizing processes across business units, consolidating product data within a shared PLM environment, and establishing analytics and governance capabilities. Only after building this digital foundation did the organization deploy AI and automation initiatives. The result was a scalable framework for applying AI to high-volume quality and change management workflows while maintaining regulatory oversight and data integrity.

Step 2: Select Scalable, Governed AI Tools

Not all AI solutions meet the governance requirements of the MedTech industry. Regulators and auditors now expect AI decisions to be explainable, traceable, and subject to controlled change management. This makes tool selection a compliance decision, not just a technology one.

Governance Matters

FDA policy materials for AI-enabled medical devices emphasize transparency, risk management, documentation, and monitoring across the total product lifecycle. MedTech organizations should ensure AI-generated outputs remain reviewable, explainable, traceable, and subject to appropriate human oversight and established quality processes.

Look for embedded AI capabilities.

Rather than building custom AI models from scratch, choose platforms with AI already embedded into quality and engineering workflows. PTC's Windchill, Codebeamer, Orbit and ServiceMax integrate AI directly into standard processes, lowering the barrier to adoption and reducing time to value.

Prioritize "glass box" AI. In regulated environments, you must be able to explain how an AI model reaches its conclusions. Avoid black-box solutions. Choose tools that provide explainable insights, so your teams can trust, verify, and document AI-generated recommendations. AI used within regulated quality and engineering processes should follow risk-based Computer System Assurance (CSA) principles to help ensure outputs remain governed, traceable, and audit-ready.

Ensure IP protection and data governance. Your product data is both a strategic asset and a regulatory obligation. Ensure that any AI tool you adopt maintains data privacy, keeps proprietary designs secure, and does not expose sensitive information to public model training.



Step 3: Integrate AI Into Existing Quality and Engineering Workflows

The most successful AI implementations in MedTech are those that feel native to the user. If a quality engineer must navigate multiple applications to access an AI insight, adoption will be slow and value will be limited.

Embed AI into daily quality tasks. Integrate AI assistants directly into the design and quality management environments your teams already use. Windchill AI Assistant, for example, enables faster retrieval of product and quality records, reducing time spent searching and ensuring teams always work with the most current, contextually relevant information.

Start with high-impact use cases and identify specific pain points where AI can deliver immediate, measurable value. This could include:

- Automating parts classification to reduce duplicates and nonconformances tied to redundant components
- Using AI-guided requirements authoring to improve quality before defects propagate downstream
- Applying predictive analytics to identify complaint patterns and prevent field escapes before they become recalls

Map AI use cases to meaningful quality outcomes. When evaluating AI, start with the patient or a specific business challenge. Define each AI use case as clearly as you would define the intended use of a medical device, focusing on a specific quality, compliance, or operational challenge. In MedTech, AI implementation should be evaluated against its impact on audit readiness, CAPA effectiveness, regulatory submission confidence, and patient safety. Prioritize use cases that deliver measurable improvements in both quality outcomes and the cost of poor quality.





Step 4: Foster Cross-Functional Collaboration Across the Product Lifecycle

AI helps break down silos, but technology alone is not enough. Realizing the full value of AI in MedTech quality requires aligning engineering, quality, regulatory, and service teams around a shared, product-centric view of quality.

Embed quality earlier in the design process. Encourage a “shift left” mentality in which quality and compliance teams are involved from the earliest stages of development, supported by AI insights that surface risks before they compound. When a designer sees a risk alert tied to a specific component in real time, they can collaborate with quality immediately to find a solution.

Validate designs earlier to reduce waste later. AI-powered simulation and generative design tools allow engineers to validate form, fit, and function virtually before committing to physical production. This proactive approach improves first-pass yield, reduces scrap and rework, and strengthens the design history file before it reaches regulators.

Automate routine compliance tasks. Use AI to handle repetitive, low-value tasks such as document retrieval, basic compliance scanning, traceability checks, and audit evidence compilation. This frees your quality managers and engineers to focus on complex problem-solving, root-cause analysis, and innovation.

Establish a closed feedback loop from the field. Connect post-market performance data, complaints, adverse events, and field actions back into design and quality decisions. AI is most effective when it can analyze these signals alongside requirements, risk, configuration, and product history to identify emerging quality trends, support root-cause analysis, and inform corrective actions before issues escalate.

Build a culture of responsible AI use. Train quality and engineering teams to effectively leverage AI within regulated environments while maintaining ownership of decisions and outcomes. Help teams understand how to interpret AI-generated insights, document AI-influenced decisions, and apply quality culture principles focused on patient outcomes and business impact. AI can accelerate work, but human expertise and review remain critical to ensuring quality, compliance, and trust.

Proven Results: What MedTech Leaders Are Achieving

Shifting quality earlier in the product lifecycle delivers measurable business outcomes. MedTech organizations that have made this shift report improvements across compliance, cost, and time-to-market metrics.

Terumo Blood and Cell Technologies (Terumo BCT) implemented Windchill® for MedDev and Codebeamer, enabling closed-loop quality management in the cloud that connects design control, quality events, and postmarket feedback within a single product record.

CONMED replaced disconnected PLM and QMS point solutions with Windchill as a unified product and quality backbone, improving audit readiness, root-cause analysis, and design robustness while reducing CoPQ.

A global MedTech leader developing cardiovascular, neuroscience, medical surgical, and diabetes care technologies **realized a 35% reduction in compliance cycle time on document gap analysis.**

These outcomes are not the result of AI alone. They are achieved when AI operates within a governed, product-centric data foundation that connects requirements, risk, verification, quality events, and field performance across the full device lifecycle.





Next Steps for MedTech Quality Leaders

The path from reactive, document-centric quality management to a proactive, AI-enabled closed-loop approach is achievable, and the regulatory and business case for making this shift has never been stronger.

Reduce Cost of Poor Quality (COPQ). Catching issues during design prevents them from becoming costly external failures in manufacturing or the field. Combined with a stronger feedback loop from post-market performance back to engineering, every product iteration is informed by real-world data, reducing recurrence, and improving margins.

Accelerate regulatory readiness. When quality records are living documents tied to the product record, not static submissions, audit preparation effort drops, first-pass approval rates improve, and regulatory outcomes become more predictable across multiple markets and jurisdictions.

Protect patient trust. When complaints and field issues are resolved faster, traced back to root causes accurately, and translated into corrective actions that improve future designs, quality stops being a compliance function and becomes a direct driver of patient safety and brand integrity.

Build a scalable quality infrastructure. As regulatory expectations continue to evolve, with FDA QMSR, EU MDR/IVDR, AI governance requirements, and UDI traceability mandates, organizations with a connected, product-centric quality system are better positioned to respond without disruption.



Begin Your Transformation With PTC

Embarking on an AI-driven quality transformation in MedTech requires a partner with deep regulatory expertise, a proven track record with medical device manufacturers, and a portfolio of solutions purpose-built for the complexities of regulated product development.

PTC embeds quality processes directly into the product record, ensuring quality events, compliance evidence, and corrective actions are always evaluated in the context of actual product data, configurations, and changes. AI capabilities are embedded within this governed product data foundation, ensuring outputs remain traceable, explainable, and compliant by design.

Our core solutions for MedTech quality management include:

 windchill [®] (PLM + QMS)
 codebeamer [®] (ALM)
 creo [®] (CAD)
 servicemax [®] (SLM)
 ptc orbit [™]

[Windchill](#) manages the design history file (DHF), device master record (DMR), nonconformances, CAPAs, complaints, audit management, and regulatory information within a unified, product-centric quality system, with AI assistants that accelerate audit preparation and record retrieval.

[Codebeamer](#) connects requirements, risk, and test management in a single environment, with AI-guided authoring, automated test case generation, and full traceability aligned to FDA, ISO 13485, and IEC 62304 expectations.

[Creo](#) delivers model-based design capabilities and AI-powered simulation to validate designs early and reduce late-stage changes.

[Servicemax](#) captures field performance data, connects service events to product configurations, and feeds post-market insights back into engineering and quality decisions, closing the loop from complaint to corrective action.

[PTC Orbit](#) unifies product, quality, and field-performance data to help organizations detect issues earlier, accelerate investigations, and reduce the Cost of Poor Quality across the product lifecycle.



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