ptc®

OPERATIONAL EFFICIENCY FOR MEDTECH MANUFACTURING

Practical strategies to streamline development, optimize the shop floor, and improve supplier collaboration.

MedTech manufacturers today are navigating a perfect storm of rising costs, regulatory complexity, and increasing demand for faster innovation. From inflation-driven labor expenses to global supply chain disruptions and tightening reimbursement policies, the pressure to do more with less has never been greater. At the same time, the industry is expected to deliver high-quality, life-saving products with precision, speed, and compliance.

Operational inefficiencies, whether in the form of disconnected systems, manual processes, or siloed teams, don't just erode margins. In a sector where precision and traceability are non-negotiable, they can compromise patient safety and delay access to critical care.

This guide is designed to help MedTech leaders cut through the complexity. Inside, you'll find actionable use cases to streamline manufacturing, reduce lead time and rework, and accelerate change cycles and delivery, all without compromising quality or compliance.

INTEGRATING MANUFACTURING WITH PRODUCT DEVELOPMENT

THE COST OF DISCONNECTION

Historically, manufacturing and engineering have operated in silos. Design teams finalize product specifications, and only then are manufacturing teams brought in to figure out how to build them. This leads to inefficiencies, rework, and delays, especially when late-stage changes are required to make a product manufacturable. With shrinking margins and a race to bring new products to market, this approach is no longer sustainable.

Disconnected processes also heighten the risk of non-compliance. With more than **8,000 global regulations** to navigate, even minor misalignment between design and production can result in costly delays, failed audits, or even product recalls. These risks are amplified by the growing complexity of MedTech devices and the need for traceability across the entire product lifecycle.

DESIGN FOR MANUFACTURABILITY

To connect these teams and break down these costly silos, leading MedTech companies are embracing **Design for Manufacturability (DFM)**, a strategy that brings manufacturing considerations into the design process from the start.

By involving manufacturing teams early, companies can ensure that products are not only innovative but also practical to produce efficiently at scale.

This integration enables faster, more informed decision-making. Manufacturing teams can flag potential issues before they become costly problems or cause delays that contribute to longer lead times. Design teams can optimize products for assembly, testing, and compliance. The result is a smoother transition from concept to production, with fewer surprises and less rework.

AGILE CHANGE MANAGEMENT

Change is inevitable in MedTech manufacturing. Whether driven by regulatory updates, supplier issues, or design improvements, managing change efficiently is essential. A robust **change management process** ensures that updates are communicated clearly, implemented consistently, and documented thoroughly.

PTC's integrated solutions enable bi-directional change management. Not only can engineering teams efficiently communicate changes downstream to manufacturing, but manufacturing teams can also initiate change requests based on real-world insights, such as components that are difficult to assemble or materials that aren't performing as expected. These requests flow back to engineering, where they can be evaluated and incorporated into the design. This closed-loop system significantly reduces change cycle times by enabling faster, more coordinated updates across engineering and manufacturing, while also minimizing errors and ensuring that every change adds value.

With integrated PLM solutions, companies have reported up to 30% reduction in change cycle time, enabling faster adaptation to regulatory shifts and market demands.

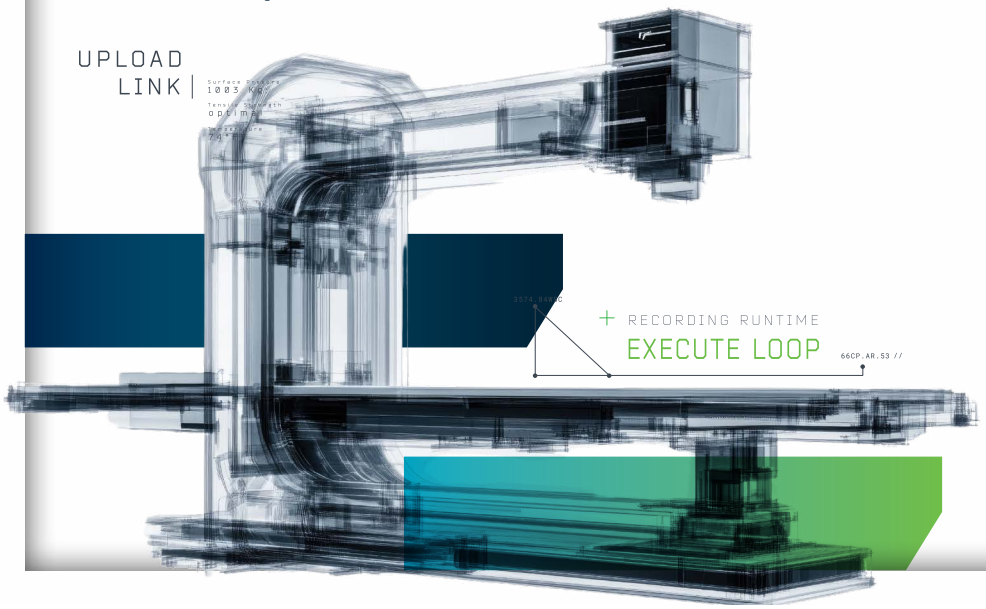
Strategy 1

LEVERAGING MODEL-BASED ENTERPRISE (MBE)

As MedTech products grow more complex and regulatory scrutiny intensifies, traditional document-based approaches to design and manufacturing are no longer sufficient. To stay competitive, manufacturers must adopt a **Model-Based Enterprise (MBE)** approach, which uses rich, digital models as the authoritative source of truth across the product lifecycle.

Model-Based Enterprise is a strategy that extends the use of 3D CAD models beyond design, making them the central reference for manufacturing, as well as quality and service. This includes:

- **Model-Based Definition (MBD): Embedding all product and manufacturing information (PMI) directly into the 3D CAD model.**
- **Digital Work Instructions: Derived from the model and tailored for shop floor execution.**
- **Closed-Loop Quality: Using model data to define, monitor, and validate critical-to-quality parameters.**



MBE provides the right data to close the gap between design and execution. Instead of relying on static 2D drawings or manually updated documents, teams work from a single, up-to-date model that contains everything needed to manufacture the product. This ensures all manufacturing information is digitally accessible and traceable. By eliminating manual handoffs, MBE also enables faster transitions from design to production, directly contributing to lead time reduction.

At the heart of this transformation is the **Intelligent Product Lifecycle (IPL)**, a seamless flow of data that connects engineering, manufacturing, and service teams. Powered by PLM, the IPL ensures that everyone is working from the same source of truth.

With a PLM-enabled IPL, teams can collaboratively define and manage manufacturing process plans, ensuring that engineering and manufacturing are aligned from the start. For example, **Fresenius Medical Care** used PTC's Windchill PLM to digitize their manufacturing process planning and change management workflows, resulting in faster approvals, improved process validating and significantly reduced change cycle times, all while maintaining compliance and quality.

Strategy 2

OPTIMIZING SHOP FLOOR EXECUTION

In the MedTech industry, the shop floor is where innovation meets reality. It's where designs are transformed into life-saving devices. It's also where inefficiencies can quietly erode margins, delay delivery, and compromise quality. To stay competitive in a high-stakes, cost-sensitive environment, MedTech manufacturers must optimize every aspect of shop floor execution.

THE HIDDEN COSTS OF INEFFICIENCY

Manual processes, disconnected systems, and outdated tools are still common across many manufacturing environments. These inefficiencies lead to:

- **Production delays due to unclear or outdated instructions.**
- **Increased rework and scrap from human error or miscommunication.**
- **Compliance risks from incomplete or inaccurate documentation.**
- **Unplanned downtime from reactive maintenance and equipment failure.**

These issues impact more than the bottom line; they can also affect patient safety and regulatory standing.

UNCOVER AND ADDRESS EFFICIENCY DRAINS WITH DIGITAL PERFORMANCE MANAGEMENT

To address these challenges, leading MedTech companies are turning to **Digital Performance Management (DPM)**. Powered by **industrial IoT**, DPM provides real-time visibility into production performance, enabling teams to:

- **Monitor key metrics like throughput, cycle time, and asset utilization.**
- **Identify bottlenecks and inefficiencies.**
- **Take proactive steps to resolve issues before they escalate.**

This closed-loop approach — analyze, identify, act— transforms the shop floor from a reactive environment into a strategic asset.

thingworx®

Leading MedTech manufacturers like **THERMO FISHER** have leveraged PTC's ThingWorx DPM to transform their shop floor operations. By gaining real-time visibility into performance metrics and bottlenecks, they nearly doubled their OEE figure in six months, demonstrating how digital tools can drive measurable improvements in efficiency and throughput.

EMPOWERING OPERATORS WITH REAL-TIME VISUAL WORK INSTRUCTIONS

Visual, model-based work instructions are another key driver of efficiency. Instead of relying on static documents or institutional knowledge, operators receive dynamic, up-to-date guidance directly from the IPL. These instructions:

- **Are derived from the latest CAD and PLM data.**
- **Include critical-to-quality parameters (e.g., torque values, tolerances).**
- **Are delivered digitally to operator workstations on the shop floor.**

This reduces errors, minimizes rework, and ensures consistent and compliant execution across production lines. Because this data is dynamic, as updates are made in one team (i.e., design changes), they are automatically reflected in work instructions and for other relevant teams.

AUTOMATING EXECUTION AND DOCUMENTATION

In regulated industries like MedTech, documentation is as important as execution. Every step must be recorded, verified, and traceable. With smart tools and connected systems, manufacturers can:

- **Automatically capture execution data (e.g., torque applied, step completed).**
- **Link this data to specific operators, tools, and product serial numbers.**
- **Store and manage this information within an electronic Device History Record (eDHR) system.**
- **Ensure audit readiness and reduce the burden of manual recordkeeping.**

Automated data capture and traceability help ensure that each step is executed correctly the first time, reducing the need for rework. Organizations have achieved significant cost savings by eliminating paper-based documentation and reducing compliance-related delays. This automation not only improves efficiency but also frees up time and resources for innovation, quality improvement, and faster time to market.

FROM DOWNTIME TO UPTIME: PREDICTIVE MAINTENANCE

Unplanned downtime is a major cost driver in manufacturing. By combining IoT sensors with AI-fueled analytics, companies can shift from reactive to proactive **maintenance for their production equipment**. This means:

- **Monitoring equipment health in real time.**
- **Predicting failures before they occur.**
- **Scheduling maintenance during planned downtime.**

With solutions like PTC ThingWorx's Real-Time Performance and Production Monitoring (RTPPM), manufacturers gain visibility into asset performance and can synchronize maintenance with production schedules. The result is higher equipment availability, lower repair costs, and more stable operations.

SUPPLY CHAIN COLLABORATION

SUPPLY CHAIN INTEGRATION AND SUPPLIER COLLABORATION

Operational efficiency in MedTech manufacturing doesn't stop at the factory floor, it extends across the entire value chain. Supply chain disruptions, fragmented supplier communication, and lack of visibility into sourcing risks can all undermine even the most optimized production environments.

20%

With supply chain costs consuming up to 20% of revenue, MedTech manufacturers must rethink how they collaborate with suppliers and manage sourcing risks.

SUPPLIER COLLABORATION WITH INTEGRATED PLM

Some comprehensive Product Lifecycle Management (PLM) solutions include capabilities that enable seamless collaboration with suppliers by allowing external partners to securely access and work with the same product data as internal teams. This eliminates the inefficiencies and risks of exchanging files via email or disconnected systems, ensuring that everyone is aligned on the latest designs, requirements, and regulatory compliance standards.

SIMULATING SUPPLY CHAIN RISK WITH AI SOLUTIONS

Advanced AI solutions that integrate with PLM can automatically analyze complex product data to help teams make smarter, faster decisions. This integration enables teams to:

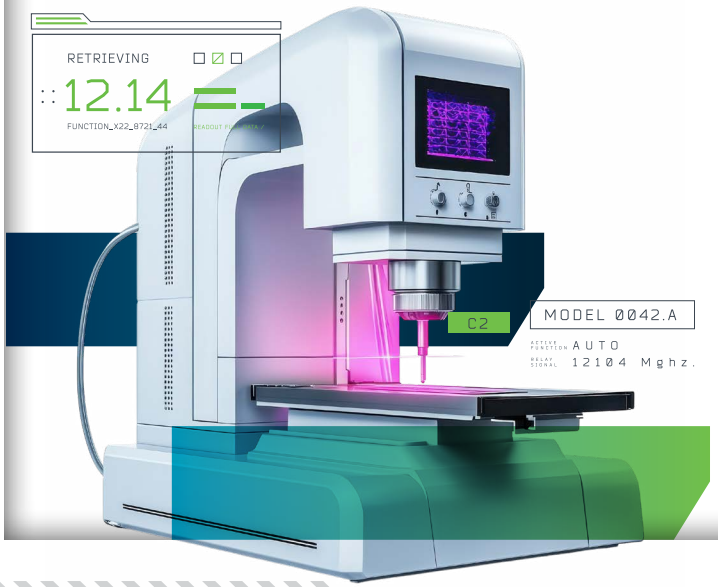
- **Analyze the compliance risks of parts and BOMs directly within their PLM.**
- **Identify potential supply chain vulnerabilities before they impact production.**
- **Make informed trade-offs between cost, sustainability, and availability, without leaving their PLM environment.**
- **Accelerate regulatory preparedness by quickly understanding material compliance across global markets.**

This proactive approach helps MedTech companies design products that are not only manufacturable but also resilient to disruption and optimized for sustainability from the start.

A CONNECTED APPROACH TO EFFICIENCY

What sets PTC apart is not just the strength of each of our individual solutions, but how they work together. Through a unified **Intelligent Product Lifecycle**, PTC connects PLM, CAD, IoT, ALM, and SLM systems into a seamless ecosystem. This integration enables:

- **End-to-end traceability.**
- **Faster, more informed decision-making.**
- **Reduced rework, improved quality, and lower total cost of ownership.**



In a world where cost and complexity are rising and margins are tightening, this connected approach is what allows MedTech manufacturers to move faster, operate leaner, and deliver better outcomes.

- **Integrating manufacturing with product development to reduce rework and accelerate time-to-market.**
- **Optimizing shop floor execution through real-time visibility, automation, and digital work instructions.**
- **Leveraging model-based enterprise (MBE) to ensure consistency, traceability, and compliance from design to delivery.**
- **Enhancing supplier collaboration to reduce sourcing risks, improve responsiveness, and ensure alignment across the product lifecycle.**
- **Deploying key technologies like PLM, CAD, and IoT to create a connected, intelligent ecosystem.**

The path forward is clear: connect your operations, empower your teams, and let data flow freely across the product lifecycle. With the **right tools** and mindset, you can reduce costs, improve margins, and bring innovative products to market faster, without compromising quality or compliance.

The **Tech-Clarity Buyer's Guide for Digital Transformation in MedTech** is your go-to resource for evaluating the tools that power operational excellence.

WHAT'S INSIDE:

- **Key criteria for selecting digital transformation technologies.**
- **Guidance on aligning solutions with your business goals.**
- **Insights from industry leaders on what drives real ROI.**

At PTC, we're proud to partner with MedTech leaders who are not just adapting to change but driving it. Together, we can build a future where operational excellence fuels innovation, resilience, and better outcomes for patients around the world.

Need more information? **Solutions for MedTech >**

Ready to Get Started? **Talk to a PTC MedTech Expert >**

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