



DIGITAL THREAD

The Problem of Data Disconnection in the Medical Device Industry

Imagine a cross-functional team working on the development of a new medical device. In the early stages, mechanical engineers design the product's housing and moving parts using simulation software to evaluate stress, tolerances, and ergonomics. This data is essential for ensuring both performance and patient safety. However, in many organizations, this information must be manually extracted and re-entered into CAD tools for detailed design. Then, it's manually transferred again to systems for finite element analysis (FEA), risk assessments, or validation protocols. Each step requires duplicate effort, often using disconnected tools.

At the same time, regulatory, electrical, and quality teams need access to accurate product data to define component placement, ensure compliance with standards like ISO 13485 or FDA 21 CFR Part 820, and prepare technical documentation. Without a connected digital backbone, this data must be re-entered manually in different systems, increasing the risk of inconsistencies, delays, or even non-compliance.

When the manufacturing team receives the final design, they often work from fragmented sources, engineering drawings, spreadsheets, emails, or PDFs, which makes it harder to ensure the design is production-ready and fully compliant. Any change made by one department requires manual updates across multiple systems and documents, leading to costly errors, rework, or gaps in traceability.

In short, key information is scattered across disconnected tools and processes. This slows down product development, hinders regulatory submissions, and creates unnecessary risk, **especially in an industry where quality, compliance, and patient safety are non-negotiable.**



Design Control



Design Excellence



Operational Excellence



Product Performance Insight



Connected Care



Closed Loop Quality & Compliance

Consequences of Data Disconnection

The absence of a centralized digital data flow in medical device design and manufacturing creates critical challenges that directly impact development efficiency, regulatory compliance, product quality, and patient safety.

Errors and rework: Manual updates between systems often result in design mismatches, overlooked risks, or version confusion.

Longer time to market: Disconnected workflows slow down iteration cycles, testing, and regulatory submissions.

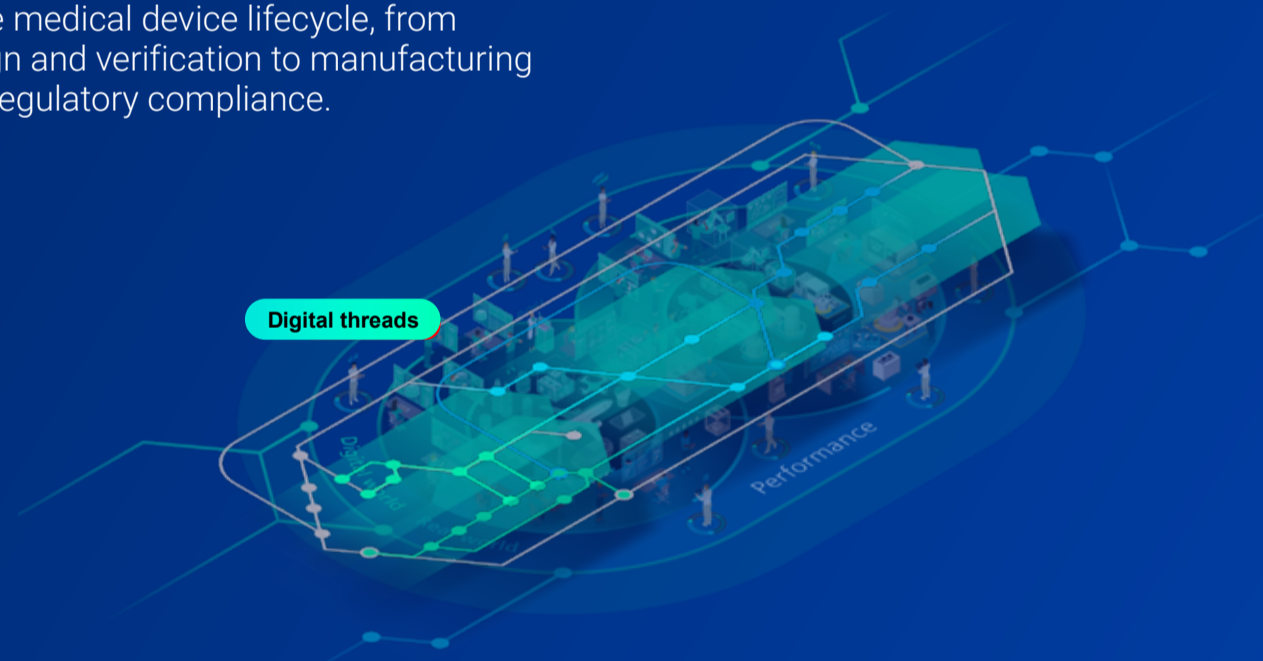
Compliance risks: Incomplete or inconsistent documentation can lead to audit findings, delayed approvals, or even product recalls.

Limited traceability: Fragmented data makes it difficult to maintain accurate DHFs, DMRs, and change histories.

Reduced collaboration: Teams operate in silos, which hinders communication and alignment, especially critical in regulated environments.

Solution: The Digital Thread

The Digital Thread addresses the challenges of disconnected data by digitally connecting all processes, teams, and tools involved in the medical device lifecycle, from design and verification to manufacturing and regulatory compliance.



Seamless data flow: Design, simulation, risk analysis, and documentation systems are fully connected. Updates made in one stage are reflected in real time across all platforms, eliminating manual data transfers and ensuring consistency.

Automation and error reduction: With an integrated environment, engineers and regulatory teams work with accurate, up-to-date information, reducing the likelihood of design errors, documentation gaps, or compliance issues.

Agile decision-making: Full traceability across systems enables early identification of risks or inconsistencies, helping teams resolve issues before they impact validation, audits, or time to market.

Improved cross-functional collaboration: From R&D and quality to manufacturing and regulatory affairs, all teams work from a single source of truth, improving alignment, communication, and speed.

Compliance and cost efficiency: Better data integrity and process integration reduce rework, simplify regulatory submissions, and ensure product quality, lowering development costs and accelerating approvals.

The risks of disconnected data don't need to slow you down. With the Digital Thread, you can streamline every stage of medical device development, ensuring compliance, improving traceability, and delivering safe, high-quality products faster.



Contact us today to discover how we can help you implement a Digital Thread in your company.