

Medical Device Engineering with PTC Integrity™

Medical device manufacturers operate in an increasingly regulated, safety critical environment, and frequently have many variants of parts, products, and product lines. PTC Integrity provides essential engineering support to equip these device makers with efficient solutions to these key business challenges.

PTC Integrity provides traceability across requirements, designs, and test protocols to address complex regulatory compliance reporting. Risk and hazard management provides coverage of risk with measurable controls and satisfies key regulatory reporting requirements of FDA CFR 21 part 820 and the European MDD. Finally, sophisticated reuse capabilities for variant management of parts, products, or product lines reduces duplicate data and rework.

Challenges

Medical device manufacturers face unique challenges that span scientific and engineering, regulatory and market domains. These include:

- **Risk Management:** Risk management activities are critical to ensuring the delivery of safe and effective medical devices. All hazards must undergo complete risk analysis to uncover potential safety or usability issues. If a risk is discovered it needs to be evaluated and, if warranted, actively managed with risk control measures. Both risks and associated control measures must be traceable to design artifacts (e.g., requirements, design specifications, test protocols) so status can be tracked and updated as development proceeds and requirements and designs are updated. Engineering teams often rely on Microsoft® Word® or Microsoft Excel® to capture these artifacts, but these tools cannot provide the traceability or visibility needed to effectively manage risk.

- **FDA DHF/DMR and European Technical File:** The FDA requires specific documentation in the form of the Design History File (DHF) and Device Master Record (DMR), while the European Union requires a “Technical File” be submitted to notified bodies. In each case, these documents consist of an assembly of engineering documentation and records including risk analysis, product requirements, design specifications, and test protocols for validation and verification as well as change control records. Producing these records, along with traceability information across records, is usually a manual and extremely time consuming and error prone effort.



- **Complexity of the Software Lifecycle:** At the core of product engineering are the systems and software development processes that connect all engineering artifacts. Software is driving innovation in the development of medical devices, which in turn adds a new layer of complexity with respect to quality, interoperability, and performance in both typical and extreme operating conditions. Mitigating the risks of this complexity requires that software components be identified, classified based on safety analysis, and directly traced to relevant design artifacts. The traceability from software component to design artifacts must actively manage any changes in requirements or designs that impact software, while the safety classification is used to determine the level of risk management required to be performed.

Solution

You are seeking a comprehensive solution—one that is capable of managing risk, ensures complete coverage of all requirements, design specifications, and software components, and provides easily navigable links to verification and validation tests to demonstrate both process and product quality. PTC Integrity offers a complete, single-solution approach where product design, risk management (as well as verification and validation activities), and artifacts are all managed in a single platform.

Device manufacturers can easily demonstrate compliance, support cross-discipline collaboration, and provide a foundation for re-use and innovation with the PTC Integrity single platform solution. The medical device solution is built on the foundation of PTC Integrity's uniquely powerful process and workflow engine, and includes configurable, quick-start process templates built to the specifications of world leading medical device manufacturers.

The PTC Integrity solution supports multiple roles on your extended product development, project management, compliance, and quality management teams, promoting transparency of information and cross-discipline collaboration:

- **Quality Assurance Managers** must document test coverage of all requirements and design specifications within a project. With PTC Integrity, demonstrating traceability and identifying non-conformities is just a click away. QA Managers can actively monitor test coverage and evaluate the maturity of the product through defect management and key validation and verification (V&V) metrics. Progress can be clearly evaluated against the stated test plan to ensure objectives are being met
- **Product and System Engineers** can easily capture requirements and design specifications along with trace relationships to other artifacts using drag-and-drop gestures. As change records are reviewed, engineers can use these traceability links to assess the impact of change and produce a detailed impact assessment report
- **Compliance Officers** can easily generate detailed traceability reports and document exports which can be used to form the Design History File (DHF), Device Master Record (DMR), or European "Technical File". These reports and document exports are generated in clicks rather than the weeks required with isolated "siloes" engineering and desktop tools
- **CIOs and CTOs** have product and project dashboards that give them the up-to-date information they need to make informed decisions, and can be confident that delivered products meet stated business goals and adhere to regulatory requirements
- **Developers** receive real-time notification of tasks assigned to them to investigate or resolve. All software changes made to fix the problem are directly linked to the defect, thus providing complete traceability between the change, defect, test, design, and requirement

“The PTC Integrity platform provides complete end-to-end requirements traceability, tests management, defect tracking, risk and hazard management, SCM, and cross activity metrics for your projects. This collection of capabilities under a unified architecture help medical device companies develop software efficiently while achieving IEC 62304 compliance.”

Carlos Almeida,
VP Engineering, SPK and Associates, LLC

Key benefits

- **Actionable, fact-based project status:** Traceability between requirements, design specifications, test protocols, change orders, and the related development activities enables teams to easily determine real time project status based on actual recorded activities instead of estimates
- **Streamlined compliance reporting:** Automated generation of document exports and traceability reports that satisfy DHF, DMF, and technical files requirements, reducing the time required to demonstrate compliance from weeks to minutes

- **Real time visibility:** Powerful querying, charting, reporting, and dashboards provide visibility into Hazards, Risks (RPN or Risk Level) requirements coverage, and overall Verification & Validation and product development status
- **Increased productivity:** Tasks that used to take engineering resources week to manually compile can be prepare with just a few clicks, enabling your most valued engineering talent to re-focus on innovation. Transparency of development assets provides a foundation for collaboration and re-use

Key features

- **Comprehensive impact analysis:** Teams can easily assess the impact of changing requirements or newly identified risks. Complete traceability coverage enables teams to quickly identify the impact of any change, while ensuring that integrity of all downstream artifacts and activities
- **Comprehensive risk management:** The PTC Integrity solution fulfills the ISO 14971 requirements for the capturing of Hazards, Risks, and Risk Control Measures. Risk Control Measures are traceable to the requirements and design specifications that implement the control measure as well as the test that validates or verifies the control measure. Charts provide exception reporting to call out unacceptable risks and unacceptable residual risks
- **Safety classification and analysis:** The PTC Integrity solution includes the ability to define software components meta-data, including safety classification and their relationships to software risks and related requirements/designs
- **Reuse for variant management:** Versioning, branching, and base-lining of requirements and other development assets at any point in the product lifecycle provides true reuse and preserves traceability where copy/paste methods fail. PTC Integrity couples requirements re-use and change management with real-time metrics and full traceability between upstream risks and hazards and downstream specifications and verification and validation activity. In addition, PTC Integrity presents all of this within a document-like interface making it easy to author and review documents and records





“As a Class II medical device, our da Vinci Surgical System is subject to regulation by the FDA under the Code of Federal Regulations Title 21. A key part of complying with this regulation is our ability to generate a traceability matrix as part of an FDA submission. The matrix for a sophisticated device such as ours might include up to eight or nine hundred interrelated documents. The generation and validation of this traceability matrix, while critically important, requires a significant human resource investment when done manually. With PTC Integrity we are able to generate these matrices in minutes with a few mouse clicks.”

Sal Brogna
VP Engineering, Intuitive Surgical, Inc

Learn more

For more information, please visit:
ptc.com/product/integrity

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