Streamline Compliance with PTC Application Lifecycle Management

Gain visibility and control over safety-critical products

Manufacturers face unique regulatory challenges. The PTC Application Lifecycle Management (ALM) solution is the only ALM solution that implements risk and safety analysis as an integral part of the product development process.

Manufacturers face unique challenges as they tackle the regulatory landscape. First, they must adhere to multiple, overlapping standards created by different regulatory bodies, each with its own approach to developing specifications and measuring conformance with these provisions. For example, medical device manufacturers fall under the scrutiny of the FDA for devices marketed in the US, and the EU Medical Device Directive in Europe. Next, regulations and associated standards are continuously evolving, requiring manufacturers to repeatedly monitor and fine-tune their regulatory response. In addition, manufacturers must demonstrate compliance across an increasingly complex product portfolio. Makers of smart, connected products, which typically combine one or more physical product variants with multiple software variants, face even greater management complexities.

Moving towards a common compliance framework

Although specific standards vary widely, industry leaders are converging on a common set of best practices that can be adapted to any set of regulatory requirements. These leaders have discovered that a common platform, which enforces process and traceability as a by-product of engineering activities, allows them to more easily adapt to multiple sets of regulatory requirements and manage their impact across evolving product lines.

Comply, improve, transform

Some organizations begin their compliance journey out of necessity. Others invest in process frameworks, such as CMMi, in order to improve the maturity of their teams. Regardless of how the journey began, nearly all organizations realize powerful benefits that extend beyond a certification checklist. Investing in processes and tools that expand visibility and control over the product delivery process realizes tangible benefits in the form of predictable product delivery, higher quality products, more productive teams, and reduced manual overhead.

> To succeed in increasingly fierce global competition, we needed to ensure traceability for requirements, including functional safety, and to introduce tools that further increase our software quality and development efficiency."
>
> Mr. Yoshihiro Miyazaki,
> Electronic Platform Technology,
> Hitachi Automotive Systems, Ltd.

Best practices for demonstrating compliance

Through our work with customers and industry experts across the regulated manufacturing spectrum, we have learned some best practices for enforcing compliance with regulatory mandates or achieving CMMi certification. These best practices can be automated through the use of ALM solutions powered by PTC Integrity. They are:

Create a foundation for compliance requirements reuse. Consider any component within your product bill of materials (BOM). The regulatory requirements the component must fulfill may vary depending on the component's country of origin, the country where it will be marketed and sold, and the product and product variant it will become part of. Now multiply that problem by thousands of components and dozens of products and product variants, and you'll quickly discover why manufacturing leaders rely on advanced requirements management solutions to manage the complex web of regulatory requirements across their product supply chain.

> PTC Integrity is the backbone of Hella's development activities. It would be impossible to facilitate projects of this magnitude, under such tight time constraints, without this solution. It allows for better, faster, and easier collaboration. Integrity has enabled us to become compliant with SPICE Level 3."
>
> Jürgen Belz
> Head of Automotive Software Standards, Hella

Yet not all requirements management solutions are capable of solving this problem. The key is how the requirements management solution enables reuse of common requirements across product lines and variants. Solutions that attempt to solve this problem by copying subsets of requirements across product sets are inherently error-prone and brittle, and ultimately fail to scale to today's modern manufacturing environments. PTC Integrity™ manages re-use through a sophisticated and self-documenting branch and re-use model. This model streamlines compliance by allowing manufacturers to proactively manage and intelligently propagate changes as products and regulations evolve.

Ensure all engineering artifacts are adequately managed, with auditable history, relation to change records, and electronic signatures. Throughout the product lifecycle, significant documentation is required by both manufacturer and regulator in order to demonstrate the existence of thorough design controls. Some manufacturers are subject to explicit regulations governing the usage of electronic signatures as specified in US Federal 21CFR Part 11. For others, consolidation of documentation into a system that supports electronic signatures is simple common sense. Too often, systems of record are distributed across emails, paper and electronic records, requirements specifications, and design documents that are maintained using Microsoft Office tools or some form of issue tracking tool. This approach, however, makes it difficult to synchronize disparate data and impossible to document that appropriate change controls were in place. Solving these challenges requires consolidation of key product documentation in one coherent platform with change control governing all assets.

Create and enforce a compliance-aware development process. Manufacturers of smart, connected products must do more than document that software meets safety-critical requirements. They must also document that the process used to develop and deliver the software was controlled. This means that only authorized users had access to lifecycle artifacts, the team building the software followed

agreed-upon procedures, and lifecycle artifacts were validated at key control points. In addition, they must assure that the development process itself cannot be circumvented through unauthorized access or changes to work products created outside of the approved process. With an auditable software lifecycle, you'll be able to provide reports that demonstrate adherence to the approved development process on demand. A customizable and process-centric workflow has the additional benefit of helping improve team collaboration and productivity. PTC Integrity provides out-of-the box process templates that can be modified to meet specific team needs, and because all development artifacts sit on a unified platform, enforcement is built in.

Gain insight and visibility through end-to-end traceability. At the core of product engineering are the systems and software development processes that connect all engineering artifacts. Quality assurance managers must ensure complete test coverage of all requirements and design specifications within a project. They should be able to easily evaluate progress against the stated plan to ensure that quality and compliance objectives are being met. Traceability is also key to managing the impact of changes, including changes to regulations and late-stage design modifications. A coherent ALM platform addresses this need by providing auditable change records with complete traceability through affected software artifacts. Built on top of an enforceable process model, these change records deliver a "single source of the truth" on the current and projected status of team activities. This insight helps organizations guide team priorities and can be included in history files to satisfy regulatory reporting requirements

Proactively manage risk. Many manufacturers subject to health and functional safety regulations are compelled to integrate risk management throughout their product design and development lifecycle. Other manufacturers choose to adopt a risk-based methodology because it provides a more holistic framework for ensuring product safety. PTC Integrity provides greater visibility into risk by documenting product hazards, risks, and risk control measures within the overall product design and development lifecycle. Not only do out-of-box templates satisfy ISO 14971 and 26262 requirements for capturing hazards, risks, and risk control measures, they also enhance safety by tracing risk control measures directly to the requirements, design specifications and (if applicable) software which mitigates them. Charts provide exception reporting that alerts teams to unacceptable and residual risks. PTC Integrity is unique in its ability to trace your risk documentation through the entire systems and software engineering lifecycle.

Automate compliance reporting. Implementing a complete, single-solution approach where product design, risk management, and verification and validation activities are managed within a single, connected framework provides a foundation for comprehensive, automated, and accurate compliance reporting. Now you can quickly and easily respond to audits with reports and documents that satisfy regulatory authorities. Powerful querying, charting, reporting, and dashboards provide visibility into requirements coverage, validation and verification activities, product development status, and, where necessary, hazard and risk analysis.

A cross-industry solution

Companies who rely on the PTC ALM solution have achieved CMMi certification across multiple levels, and have achieved TÜV SÜD Automotive GmbH certification. The PTC ALM solution powered by PTC Integrity is the ideal solution for implementing the following regulatory requirements and standards:

Regulation/standard	Scope	Impact for software and systems teams
ISO 14971	Requirements for an application of a risk management system for medical devices	Requires engineering teams to provide evidence of traceability between risk analysis and product design documentation
ISO 13485	Quality management for medical devices	Demands a defined and integrated process for product development from concept through end-of-life
IEC 62304	Software lifecycle process for medical devices	Demands a defined and integrated process for software development
FDA 21CFR Part 820	Quality management for medical devices sold and distributed in the US	US regulatory requirement that specifies the quality management requirements, placing a demand on a defined and integrated process for product development
FDA 21CFR Part 11	Regulatory requirements for electronic records	US regulatory requirement that requires engineering teams to provide evidence that electronic records are authentic and reliable, ensuring that electronic signatures are fully equivalent to hand-written signatures in all areas where signed records are required
CMMi	Capability Maturity Model, Integrated	A multi-level model for improving the process maturity and capability of software teams. This specifies practices and competencies required in software development as well as a framework for measuring and improving your process. This places a demand on defined and integrated processes, management of development assets, metrics gathering and reporting, and traceability across assets
ISO 26262	Road vehicles – functional safety standards	Specifies processes for integrating risk and hazard analysis into automotive product, system, and software development, requiring domain-integrated traceability
IEC 61508	Functional safety of electrical/electronic/programmable electronic safety-related systems	Specifies processes for integrating risk and hazards analysis into electrical product design, system, and software development, requiring domain-integrated traceability
ISO / IEC 15504	Automotive Software Process Improvement Capability Determination (SPICE)	Specifies a reference model and assessment approach for developing software in select industries; widely used by automotive industry
DO—178B/C	Software considerations in airborne systems and equipment certification	Specifies software lifecycle artifacts required in developing software used in airborne systems, requiring specific practices and competencies that are enhanced through traceability and a defined lifecycle process

PTC®

“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.

Take the next step

PTC has helped hundreds of organizations comply with regulations, improve their team capability, and transform their business. For more information about PTC ALM solutions for regulatory compliance, please visit PTC.com or contact your local PTC account representative.

J3423–ALM Compliance–TS–0214