

Regulatory compliance

Control the risk and cost of regulatory compliance

Benefits

- Design products that can be sold anywhere in the world
- Assign ownership, enforce control and ensure accountability
- Proactively plan for and meet future regulatory directives
- Protect IP and audit information access
- Reduce downstream risks and costs by building compliance into your product development process

Features

- Solid foundation for information management, secure access and retrieval
- Business process visibility and compliance traceability
- Identification and control of metadata (e.g. valid value lists, role based user interface)
- Executive management awareness and enforcement capabilities
- Regulatory compliance reporting tailored to specific industries
- Supplier portal to facilitate information-gathering, ensure partner confidence, and protect intellectual property (IP)
- Authoring management facilitated by advanced Microsoft Office integration



Summary

There seems to be no end to regulations; they are growing in number, complexity, and scope. The costs of achieving and maintaining compliant products are high, but the costs of non-compliance are even higher. Non-compliant products can lead to legal actions, lost customers, fines, lost revenue and/or exclusion from key regional markets. How do you keep up with the rapidly changing regulatory landscape while bringing innovative new products to market? With a comprehensive product lifecycle management (PLM) strategy, powered by Teamcenter® software from Siemens PLM Software.

Teamcenter takes control of regulatory compliance management

Teamcenter helps you document, enforce and track product regulatory compliance throughout the entire product lifecycle. With its secure and robust knowledge management framework for document management, configuration management and audit tracking, Teamcenter helps support regulatory compliance mandates across multiple industries, including:

- Medical device compliance (US FDA - 21 CFR Part 11, 21 CFR Part 820)
- Machinery safety compliance (US OSHA 1910.212, EU DIRECTIVE 2006/42/EC, UK 2008 No.1597 Part 3)
- Configuration and change management (CMII)
- Export control (ITAR)

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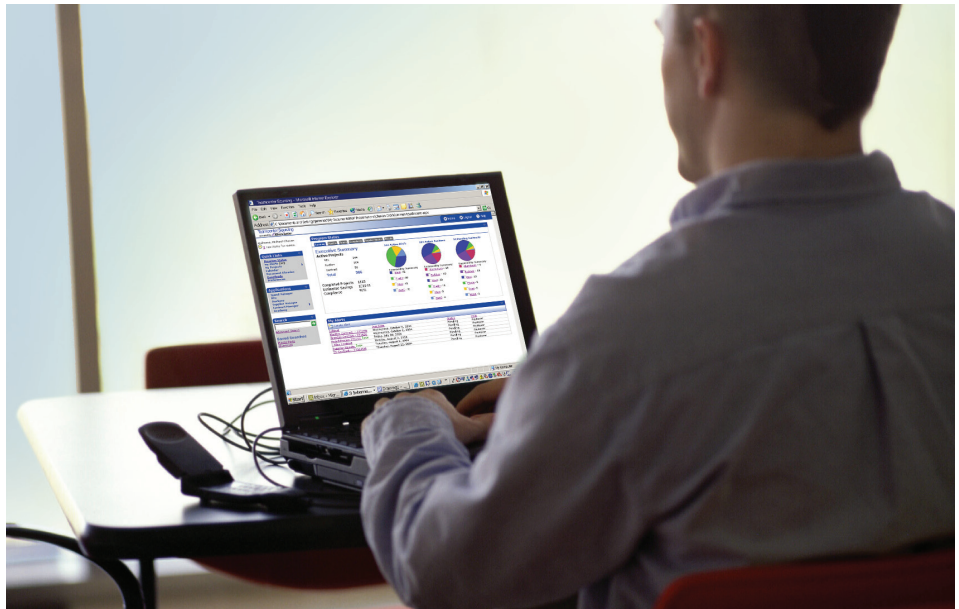
Answers for industry.

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Features *continued*

- Schedule management with phase gates and tightly integrated workflows
- Document and template management
- Configuration and change management
- Subscription and notification services
- Up front risk management capabilities (QFD, FMEA, etc.) with requirements management and Systems Engineering



With the aid of Teamcenter, you can clearly document and manage regulatory requirements through consistent processes and by tracking accountability. Standards and regulatory checks can be undertaken as part of your everyday workflow processes, minimizing disruption and maintaining productivity. You can embed regulatory compliance into lifecycle processes seamlessly, with minimal impact on cost, quality and time-to-market.

It's all about information management

Some regulations are specific to particular industries. Some are specific to individual countries. Some are common to U.S. companies – whether they operate solely domestically or internationally. Based on their industry, companies are required to prove compliance with different regulations at different stages in a product's lifecycle.

As different as the individual regulations may be, they all have some compliance issues in common – and these demand the establishment of automated systems and processes to handle the documentation necessary for compliance. The first step consists of understanding that compliance is a manageable process. Companies clearly need to invest in a compliance framework to meet these demands.

It makes sense to employ product lifecycle management (PLM) software, probably already in use or under consideration, to manage the product-related information across internal disciplines and departments and to manage compliance with regulations that govern different stages of the product lifecycle. The tools required for both kinds of management processes exist in well-designed PLM systems.

Many people need access to the documents and records that provide evidence of compliance, so that they can all work together to support it. This holds true for design engineers, manufacturing engineers, sourcing and procurement personnel, as well as top executives. Only in that way can the corporation be sure of individual employee accountability for compliance throughout the product lifecycle.

Schedules with embedded workflows can ensure that the right resources are assigned to tasks. Role based user interfaces along with a robust security model ensure the control of intellectual property. Complete visibility into processes and strong reporting capabilities can help companies stay compliant and help users to stay on track with deliverables. Leveraging document templates can help to ensure that users are adhering to regulatory requirements.

Compliance need not impact costs and time-to-market

Responsibility for ensuring regulatory compliance is part of the job descriptions of chief financial and operating officers – and certainly CFOs and COOs will be held responsible by the company. The chief information officer (CIO) is normally responsible for finding and deploying technology to support compliance efforts. From there, the accountability hands off to the various departments involved in product development.

Regulatory requirements need to be treated the same as any other product requirement – as essential criteria that must be met for products and companies to succeed. Failure to meet these criteria can mean the loss of contracts, the loss of customers and ultimately, the loss of jobs. Another way to look at compliance is as a framework for accountability throughout the whole product lifecycle – from early product development, to maintenance, to obsolescence and even to end-of-life processes that have to be documented.

A spokesman for a global electronics manufacturing company pointed out that the management of information for regulatory compliance is similar to that for managing quality in a program based on Six Sigma. The latter requires adherence to a strict set of processes and metrics, which the company's PLM system has helped the organization standardize. The same applies to compliance with a variety of financial and governmental regulations. "We can store all standard operating procedures in the system, so that different authorized people can pull down anything necessary to ensure regulatory compliance," he said.

Similarly, an IT executive for a manufacturer of medical products recently reported that his industry is faced with frequently changing regulations from the FDA – and that the company depends on its PLM system to pull information together to help meet the need for regulatory compliance documentation, and to keep pace with changing requirements

The more companies integrate lifecycle steps into the corporate compliance process, the easier it becomes to manage compliance and the less costly it is. And, clearly, the management system chosen needs to have the flexibility to handle the specifics for each industry, each set of products and each set of regulations. It also needs to have the tools necessary to adapt to changing business environments.

The bottom line on regulatory compliance is ownership of the process and the tools. Each company has to comply: the risks of non-compliance are simply too high. Every corporation needs to meet hard deadlines for compliance in an environment of heightened scrutiny. With those facts in mind, it pays for organizations to perform the process correctly, using a stable, scalable PLM architecture that leverages and protects previous IT and regulatory compliance investments.

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