SIEMENS

Answers for industry.

Compliance management for medical devices

Benefits

- Facilitates integrated end-to-end compliance traceability and reporting
- Accelerates time to compliance
- Enables companies to establish and maintain a validated state of control
- Enables companies to capture and manage regulatory requirements from concept through disposal
- Reduces risk and costs associated with noncompliance
- Shortens product development cycles by requiring fewer design iterations
- Facilitates enterprise compliance status and reporting
- Replaces hard copy documents with secure electronic information

Summary

Teamcenter® software provides the most holistic and integrated cross-discipline solution for end-to-end management of the medical devices industry's product lifecycle. Flexible and easy to use, Teamcenter combines a robust set of compliance management, traceability and reporting capabilities to deliver the industry's best solution for medical devices manufacturers facing strict regulatory requirements, increasing competition and demanding time-to-market pressures.

Accelerating regulatory compliance in the medical devices industry through persistent traceability during design

Teamcenter plays an important role in helping medical devices and diagnostic equipment companies significantly reduce the time it takes to prove compliance with regulations established by national agencies that regulate the design, manufacture and use of medical devices, such as the U.S. Food and Drug Administration (FDA). Teamcenter enables companies to fully trace all activities leading to the manufacture of medical devices by automatically linking compliance requirements with engineering and specification data.

The Teamcenter medical device solution facilitates comprehensive program lifecycle management, which in turn results in faster design cycles, accelerated time to regulatory agency approval, fewer design and submittal iterations and lower costs for design, development, manufacturing, testing and tracing. In addition, these advantages translate into greater market endorsement and extended corporate good will.

Business context

In the United States, the FDA is responsible for regulating food, drugs, medical devices, biologics (vaccines, blood products), animal feed and drugs, cosmetics and radiation-emitting devices. Essentially, the FDA has the authority to prevent any entity from exposing the public to harmful products, substances and processes as detailed in the

Compliance managment for medical devices

Benefits *continued*

- Easily integrates globally dispersed compliance activities into a single seamless, easy-to-use system

Features

Single source of product and process knowledge that enables:

- Automatic device master record (DMR) links between product documents and device design
- Automatic DMR creation/ maintenance
- DMR validation against FDA guidelines
- Rule-driven document retrieval
- Product/process documentation links
- Structured approach to failure modes and effects analysis (FMEA) and risk management
- Automatic traceability through compliance and audit reports
- Ability to integrate compliance information into standard business processes
- Responsibility tracking for enhanced security
- Dynamic PDF and digital signature generation for document authentication
- Dynamic stamping/ watermarking to validate documents with part attributes and drawing templates

U.S. Code of Federal Regulations (CFR) administrative law. Two key sections of this code are especially crucial to the medical devices industry.

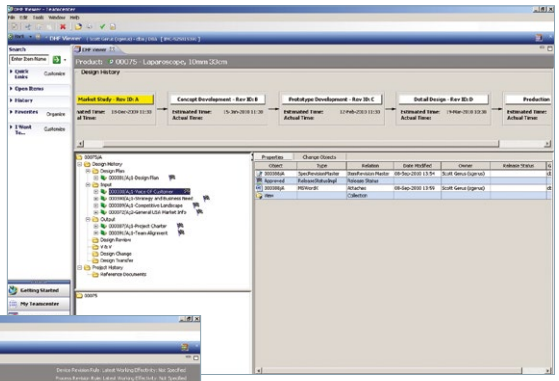
- 21 CFR Part 11, Electronic Records and Electronic Signatures
- 21 CFR Part 820 Quality System (QS) Regulation

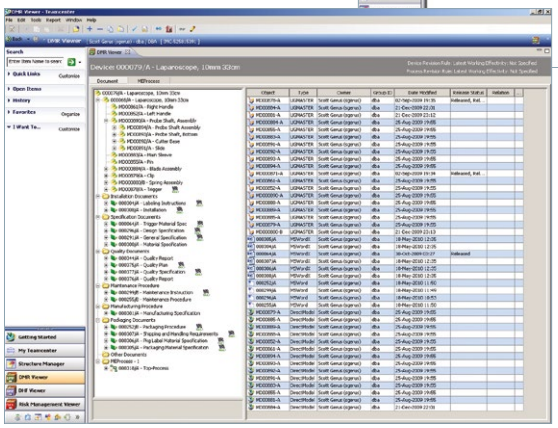
Guarding the health and safety of consumers and complying with regulations set forth by the FDA and other national regulatory agencies are time consuming, complex and extremely costly activities unless they are implemented as part of a comprehensive product lifecycle management strategy.

Teamcenter facilitates this strategic approach by tracking all of the product data that pertains to product development activities performed by a medical devices OEM and its suppliers. By integrating compliance management into a complete product lifecycle, Teamcenter virtually eliminates manual data entry, improves data accuracy and reduces the costs of both compliance and noncompliance.

Key capabilities

To enable medical devices companies to comply with regulatory agency requirements, Siemens PLM Software provides an off-the-shelf solution driven by affordable and easy to deploy capabilities. Teamcenter unifies the entire medical devices product lifecycle from product ideation through product retirement. The Teamcenter solution takes a holistic approach to compliance management that captures, manages, tracks and reports on a device's regulatory requirements as these requirements evolve across a product lifecycle that includes an enterprise's design, manufacturing, test and service operations.





Features *continued*
End-to-end requirements visibility through:

- In-process design history file (DHF)
- DHF reporting (slippages/ validations)
- Stage-gate processes with milestones, mandatory documents and effort spend
- Validated/verified product development processes
- Independent product/ document change management
- Integrated corrective action and preventive action (CAPA) functionality
- Links between CAPA and other engineering processes
- Ability to link multiple issues to single CAPA action
- Dashboard viewing for preventive action
- Full traceability between revised components and issues necessitating their change

Teamcenter leverages a high level systems engineering approach with tight change management controls to make certain that all design, manufacturing and test processes have been qualified and deemed suitable for use – as well as that all operational methodologies have been validated to affirm that they can, and actually have, performed their declared functions.

Teamcenter ensures correctness at every step in the product lifecycle – thereby reducing the number of design iterations that need to be performed and accelerating time to device approval. Fewer iterations also lower product cost while accelerating market delivery – all of which improves a company's ability to compete.

Built on an industry-leading distributed and modular service-oriented architecture (SOA), the Teamcenter medical devices solution unifies all of the disparate sources of product, process and compliance information in an enterprise, including its PDF, XML, J2EE-compliant web applications and back-end data sources.

The Teamcenter architecture also reflects Siemens PLM Software's commitment to "green" product development. By designing environment compliance into its own products and by using manufacturing processes that protect the environment, Siemens PLM Software provides integrated tools that establish Good Manufacturing Processes (GMP) upfront.

Most importantly, Teamcenter enables medical devices companies to establish regulatory compliance as a strategic initiative. Companies are able to integrate the Teamcenter solution into their existing supply chain, design and manufacturing systems to support efficient data collection, reporting and traceability.

Teamcenter robust capabilities and integrated features establish the industry's premier quality assurance environment for creating, managing, controlling, tracking and distributing all of the electronic product records associated with the medical devices lifecycle.

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