

Cross-User Options

SMARTTEAM Regulatory Compliance Framework (RCF)

SMARTTEAM V5R18





Cross-User Options

SMARTEAM - Regulatory Compliance Framework

To provide a working environment that accelerates the process by which organizations verify their compliance to industrial regulations, such as FDA - 21 CFR Part 11.

Product overview

SmarTeam Regulatory Compliance Framework provides companies with tools to ensure and facilitate

- ❑ Management of access authorization within the working environment
- ❑ Database traceability
- ❑ Electronic signatures within approval processes

SmarTeam Regulatory Compliance Framework enables:

- ❑ A collaborative PLM solution for various industrial markets, both Windows and Web based environments
- ❑ Accelerated compliance with industry-specific regulations, such as FDA 21 CFR Part 11
- ❑ Process-driven digital signoff with Electronic Signatures
- ❑ Audit Trail - full tracking and querying of system activities
- ❑ Automated and standardized workflow processes
- ❑ Enhanced security Built-in controls for strict authentication
- ❑ Automatic mail notifications
- ❑ Batch printing

Product Highlights

- ❑ **Supports Web and Windows**
- ❑ Enhanced user security mechanism, for authenticating product records

- ❑ Audit trail of changes generated electronically and accessible instantly for review
- ❑ Comprehensive and flexible handling of electronic signatures for authorized users
- ❑ Automatic mail notifications
- ❑ Batch printing with embedded electronic signature information
- ❑ Streamlines the regulatory compliance approval process

Product Key Customers Benefits

Supports organizations needs for compliance with certain industry-specific regulations by:

- ❑ Helping organizations to avoid regulatory warnings, delays, and fines related to the development cycle, through built-in best practices that may be applicable to their compliance.
- ❑ Being an open system, in accordance with certain industry requirements
- ❑ Manages general and secured data in the SmarTeam database
- ❑ Is easily accessible and instantly presentable to the certifying agency

In addition to providing the regulatory benefits described herein, SmarTeam - Regulatory Compliance Framework:

- ❑ Provides a collaborative Product Data Management solution
- ❑ Leverages industry-leading SmarTeam PDM tools with the full scope of information regarding compliance with industry-specific regulations.

- ❑ Facilitates innovation and collaboration between product engineers and across the extended enterprise, allowing companies to track, monitor, and review the complete history of drawing revisions and design documents
- ❑ Optimizes and accelerates the development process, shortening:
 - ❑ Time to submission
 - ❑ Time to approval
 - ❑ Time to production
- ❑ Integrates tightly with existing MS Office and multi-CAD systems

ABOUT SMARTEAM V5R18

SMARTEAM manages and leverages corporate product knowledge and links it with business processes.

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