

LIFE SCIENCES LICENSE FOR DOCUMENT CONTROL

Reduce Risk and Ensure Compliance with a Global, Scalable Solution



INDUSTRY CHALLENGES

Regulated companies live and die at the hand of being first to bring a “best in class” product to market rapidly without jeopardizing compliance. Companies must ultimately achieve mature product quality with a low compliance burden. **License for Document Control** establishes and enforces company standards to enable consistent development and production of high-quality products that will meet or exceed regulatory and quality requirements.

License for Document Control automates and effectively manages the enterprise change management, review release, training, and distribution of approved documents. **License for Document Control** simplifies the document change and revision process, and more importantly, reduces risk associated with the use of erroneous and outdated documents.

SOLUTION HIGHLIGHTS

License for Document Control automates and effectively manages the enterprise change management, review release, training, and distribution of approved documents. It simplifies the document change and revision process, and more importantly, reduces risk associated with the use of erroneous and outdated documents.

Proposed changes are evaluated, justifications are documented and change plans are defined and executed. Change approval assignments are configured for reviewer and approvers that require electronic signatures to release approved documents across the business. The change management process is implemented to ensure consistent multiple site implementations of the approved document based on effectivity dates that support periodic reviews to ensure on going compliance and accuracy of the document intended usage.

License for Document Control can ensure and record that all effected locations and staff are aware of changes and trained with new or revised control documents. For each new or revised document that is released, the system automatically sends email notifications to personnel who are affected by the released controlled document. The automatic training process engages staff for acknowledgement when documents are approved, and requires electronic signatures with read and understood statements to verify stakeholders have performed any related mandatory training tasks.

License for Document Control supports:

- 21 CFR 820 Quality System Regulation (GMP — Good Manufacturing Process)•
- 21 CFR 11 (ERES — Electronic Records and Electronic Signatures)
- ISO 13485 (Clause 4) for establishment of a Quality management system

End-to-End Document Control and Training Management

License for Document Control helps ensure that the right people have access to the right information at the right time. It manages all aspects of the change management process including tracking from the point the change is created to the time it is implemented internally or globally. Automated routing for approvals and escalations for overdue tasks and document control cycle times can be significantly reduced.

Process Standardization with Templates

License for Document Control can securely automate routing, escalation, approval, and delivery of standard operating procedures, policies, and other documentation by providing the user the ability to create clearly defined templates. Document and change templates allow users to standardize documentation by providing a convenient starting point for document management using corporate standards. The system automatically maintains a fully compliant, detailed electronic archive of all templates. Change request templates support impact questionnaires that provide guidance to assist users in configuring change orders for processing.

Streamline Workflows

License for Document Control provides a centralized control of the process with integrated collaboration, review, and approvals from designated subject matter experts. Feedback on the effectiveness of proposed changes and change plans requested are tracked and monitored, helping to ensure that changes are properly planned and will deliver the expected results before they are rolled out across operations.

Tracking Controlled Documents and Training Management

License for Document Control notifies trainers and trainees automatically upon completion of assigned tasks. Seamlessly pairing control document management with training, engages staff to acknowledge when documents are approved or revised and requires their electronic signature to verify that the related training assignments have been read and understood.

License for Document Control provides a simple way to schedule and record training for the organization. Users can easily view their responsible documents, templates and periodic reviews that require their attention. Users can leverage document filtering to access released documents, responsible organization, subject matter expert, implementation organization, and responsible person.

Collaboration & Approvals

Users can benefit from a wide range of capabilities for global enterprise collaboration—manage and organize shared documents and structured product data; create digital workspaces for virtual teams, enable users to easily raise issues, organize meetings, and track decisions. Any object lifecycle modifications can be formally approved using routes defined by end-users or from standard route templates.

Microsoft Integration

Users can create and access **3DEXPERIENCE®** data from the most popular Microsoft applications: Word®, Excel®, PowerPoint®, Outlook®, Windows Explorer, and Windows Desktop Search. This capability enables enterprise-level collaboration while not disrupting the established productivity of end-users. With product content being managed in **3DEXPERIENCE** rather than on users' PCs, organizations are able to create, manage and review product content more securely.

SOLUTION VALUES

- Complete end-to-end control document management
- Dynamic links to related documents and data for improved up-to-date visibility and traceability
- Templates to promote standards
- Periodic review management for continuing suitability and compliance
- Enterprise change management to drive standards and consistency across the global enterprise
- Defined training processes with clear views of training status
- Full traceability and auditable document
- revision control
- Support for Electronic Signature - CFR 21 Part 11

LICENSE TO CURE FOR MEDICAL DEVICES

License for Document Control is part of **License to Cure for Medical Device**, a Dassault Systèmes Industry Solution Experience based on the **3DEXPERIENCE** platform that allows companies to eliminate scattered processes and data and to “embed” regulations as an asset, optimizing quality and compliance and reducing cost and time to market.

This end-to-end solution supports all aspects of a medical device company’s quality system and regulatory compliance ISO-regulated design controls.

Our 3DEXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the 3DEXPERIENCE® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes’ collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 190,000 customers of all sizes in all industries in more than 140 countries. For more information, visit www.3ds.com.



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