DHC VISION

DHC VISION SOP & Training Manager

Regulatory Compliant Document Management

In the pharmaceutical and medical device industry, special care is required when managing documents, not least in the case of standard operating procedures (SOPs). Global enterprises in particular must demonstrate compliance with a multitude of laws and regulations, e.g., in relation to production processes. The GxP guidelines issued by the US Food and Drug Administration (FDA) and the European Medicines Agency provide stringent frameworks for statutory compliance with document management requirements.

Paperless administration of company documentation is just one of the core functions in DHC VISION SOP & Training Manager. It supports all aspects of regulatory compliant document management, from creation and editing to approval, distribution, training, and archiving. The use of electronic signatures facilitates complex approval processes that are also fully traceable. Finally, but no less importantly, it is also possible to plan and document regular training measures – an area that is often neglected.

DHC VISION SOP & TRAINING MANAGER SUPPORTS

- **Authors** when creating and editing documents, editing applicable appendices and non-administered or informal information, processing reader comments, and approving documents.
- **Reviewers and approvers** when reviewing and approving documents or extending/terminating their validity.
- **Training managers** when evaluating, coordinating, and tracking training requirements, or when defining training profiles by assigning instructions and training content to employees.
- **Readers** by providing fast and direct access to relevant documents via intelligent dashboards. Required documents can be assigned to specific individuals for reading and comments.
- **Translators** by enabling quick and convenient translation of documents including all relevant metadata.

BENEFITS

- GxP-compliant document management
- Transparent view of documents, training activities, processes, and organization
- Easy identification of change requirements
- Fast access to current documents and information
- Easy enterprise-wide rollout of documents/translations

HIGHLIGHTS

- Role- and task-specific dashboards for SOP management and training
- Audit-proof document management with version and change history
- Granular permissions concept
- Configurable workflows for reviewing and approving documents using electronic signatures
- Organization and documentation of training based on employee profiles

"The processes we use to approve and distribute SOPs have been significantly simplified, which means we now rarely find issues during audits."

Head of Quality Management

DHC VISION
SOP & TRAINING MANAGER

- ✓ Fast results
- ✓ Easy collaboration
- ✓ High user acceptance
- ✓ Reduced workload
- ✓ Individual, transparent, and secure

DHCVISION

DHC VISION – software for process management, quality, and GRC

DHC VISION is an integrated enterprise management system for use in process management, quality management, and GRC (governance, risk, and compliance). It combines the core disciplines of process-oriented control to create a powerful solution for successful corporate management. Thanks to its modular design, DHC VISION enables the phased implementation of a single information system that covers all aspects of your organizational and management structure. With more than 15 years of successful deployment across a wide range of sectors, DHC VISION solutions and products can help you achieve your goals.

Find out more about the other DHC VISION solutions and products for **process management, audit management,** and **CAPA management.**

DHC VISION received the INNOVATIONS-PREIS-IT ("IT Innovation Prize") in 2009, 2013, and 2014 and the Process Solutions Award in 2012 for the design and execution of its modular solution concept.

Join our **free webinars** and find out more about the latest developments in process-oriented corporate management.

For more information, please visit www.dhc-vision.com

FEATURES IN DHC VISION SOP & TRAINING MANAGER (selected)

Document creation and management

- Linking of documents to other objects, e.g., processes, organizational units, application systems, and products
- User dashboards with document information, training catalogs, and training requirements
- Integration of Microsoft products (Word, Excel, PowerPoint) and all other document formats
- Integrated template management for creating documents
- Assigning of attributes to documents (e.g., type, scope, standards, keywords)
- Integrated full-text search for document content and attributes as well as all other company information
- Simplified translation of documents including formal approval of translation
- Intelligent client and permissions concept for enterprise-wide document and training management

Document control and approval

- Definition of authors, co-authors, reviewers, approvers, and distribution lists
- Workflow-based review and approval of documents using electronic signatures
- Readymade best-practice approval workflows
- Easy customer-specific modeling and configuration of approval workflows
- Real-time publication after approval
- Audit-proof management with version and change history
- Reminder/escalation mechanisms for monitoring documents with limited validity

Training and training management

- Definition of training profiles based on employee profiles, jobs, or roles
- Employee dashboard with real-time display of personal training requirements
- Training on standard documents via self-learning content or classroom training
- Automatic notification of training required after document updates, also for staff without PC
- Planning and documentation of training modules for classroom training, especially for regular scheduled training
- Automatic generation of training reports and certificates
- Convenient post-training feedback and easy scheduling of subsequent training sessions
- Extensive reporting functions for monitoring and tracking employee training requirements

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