M-Files QMS is an out-of-the-box solution for daily quality management

With M-Files QMS, all quality documents and data are linked together within a single system, enabling organizations to optimize quality processes while streamlining compliance activities and audit requirements.

"We use M-Files for all of our specific ISO documentation as well as our final designs."

-Henrik Lyder
Principal,
Bentley Instruments

M-Files QMS help your organization:

- Meet quality certification requirements (ISO 9000/9001, CE labeling, etc.).
- Manage documentation requirements for compliance with laws or regulations.
- Achieve smoother and more efficient periodic audits.
- Manage all information related to manufacturing quality-intensive products or services.
- Reduce risks of financial loss, missed timelines, safety issues or reputation damage.

Practical tools for *daily* quality management:

- **Simple to deploy and use.** Native Windows user interface is instantly familiar.
- **Gain control of your content.** Single centralized repository for all documents and emails.
- **True database engine.** Efficiently combines documents, process information and metadata.
- **Robust out-of-the-box functionality.** Comprehensive solutions for managing quality-related documentation, tasks, processes and responsibilities.

www.m-files.com/qms

M-Files QMS Modules:

- Document Control
- Personnel Database
- Training Management
- Building Inventories
- Quality Assurance
- Repeating quality tasks
- Tracking Subcontractors and Suppliers

M-Files Deployment Options:
Cloud
On-premise
Hybrid

"By using M-Files to automate processes and implement strict workflow procedures on critical documents, we've radically reduced the number of manually introduced errors, resulting in higher quality products and improved profitability."

-Fredrik Albertson
General Manager,
Fläkt Woods

M-FILES QMS FEATURES TWO CONFIGURATION OPTIONS:

One for manufacturers requiring compliance with ISO standards, and another for manufacturing organizations in highly regulated industries such as pharmaceutical, medical devices, chemicals, transportation, etc. that must comply with regulations such as FDA CFR Part 11.

M-Files QMS

- For compliance with ISO 9001:2008
- SOP management (templates, workflows, processes)
- CAPA / NCR management
- Employee training and qualification records
- Quality Manual templates
- Instructions and recommendations for ISO 9001:2008 audits
- Audit trail to track changes in documents and records

M-Files QMS for Regulated Industries

- For compliance with regulations, such as FDA 21 CFR Part 11 and EU Annex 21
- SOP management
- CAPA and NCR management
- Digital and electronic signing capabilities
- Employee training and qualification records
- Full audit trail required by FDA 21 CFR Part 11
- Calendar view
- Reporting for analysis and business intelligence

Improve Quality Systems and Meet Quality Certification Requirements

- Award-winning Electronic Document Management System (EDMS) for storing and organizing all quality-related electronic files, scanned paper documents, email messages and other vital data.
- Flexible and easy to configure for the unique and specific needs of individual businesses.
- Preconfigured templates for quality processes and workflows covering common quality requirements and policies (such as ISO 9001).
- Built in reporting engine and calendar designed to instantly notify key QMS users about ongoing, near future, and overdue quality tasks.
- Location independent with support for browser only and mobile devices for anytime, anywhere access to critical quality information.

Robust compliance, quality and security capabilities:

- **Compulsory and automatic version history** for all content provides easy access and roll back to prior versions.
- **Mandatory workflows** for any document or record.
- **Patent-pending automatic metadata driven permissions** ensures secure access to sensitive information.
- **Automated backup** capabilities protect your data.
- **Soft delete** enables recovery of deleted content.
- **Full time-stamped audit trail and event log** maintains a record of all end-user and system admin actions.

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