

FUNCTIONAL OVERVIEW

M-Files QMS 2018 is a flexible, scalable out-of-the-box solution for quality management.

Organizations operating in highly regulated industries seek a balance between maintaining compliance and usability.

M-Files QMS takes the next generation of enterprise information management (EIM) and provides a rich set of features to ensure that all quality documents, data, and processes are linked together within a single, compliant and easy-to-use system. This enables organizations to optimize quality processes and provide evidence of the efficiency of the quality system for auditing purposes.

"If you do ISO 9001 manually, the additional paperwork is a pain, but using M-Files, its trivial" - Howard Loewen, President MicroPilot

M-Files QMS Helps Your Organization:

- Improve operative performance and customer satisfaction
- Integrate risk management and quality capabilities into daily business practice
- Meet requirements for regulations and standards such as ISO 9001, HIPAA, Sarbanes-Oxley, FDA 21 CFR Part 11, and several GxP regulations including EU GMP Annex 11.
- Manage all information related to the quality system
- Automate quality processes like risk management, change control, CAPAs, and training while verifying that procedures are followed
- Ensure smoother and more efficient internal and external audits
- Reduce risks of financial loss, fines from regulatory agencies, missed timelines, safety issues or damage to you company's reputation

M-Files Provides a Practical Set of Tools for Integrated Compliance and Quality Management:

- An easy to use, single solution for all quality processes
- Control your content with a single, centralized repository for all documents and emails
- With robust out-of-the-box functionality this comprehensive solution allows organizations to manage quality related documentation, tasks, processes and responsibility
- Native apps for desktop and mobile provide optimal user experience for each device type

"Our company is audited throughout the year, from customers conducting quality assurance inspections to our quarterly financial audits--and with M-Files, we spend far less time administrating audits." - Tyler Lassen, Idaho Milk Products

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AN AWARD WINNING SOLUTION FOR QUALITY AND COMPLIANCE

M-Files QMS is for organizations operating in highly regulated industries such as financial services, pharmaceutical, medical devices, chemicals and transportation requiring compliance with regulations and standards such as HIPAA, Sarbanes-Oxley, ISO 9001, FDA 21 CFR Part 11 and EU Annex 21.

M-Files is Deployment Options include:
Cloud, On-Premises, Hybrid

Secure, Robust Quality and Compliance Capabilities

- Metadata-driven permissions ensure secure access to sensitive information
- Automated version control for all content
- Mandated workflows for documents and processes
- Preset backup capabilities ensure data is secure
- Soft delete enables recovery of deleted content
- Watermarks keep printed documents under control
- Time stamped audit trail and event log maintains a record of all system actions
- Automatic numbering and naming rules to accurately identify documents
- Training requirements automatically generated and learning is tracked

"We recently completed two external ISM code audits. Both auditors independently praised our use of M-Files in regard to documentation control and to the fact that our quality manuals were the most up-to-date." - Andrew Daily Managing Director, Inco Ships

M-FILES QMS OUT-OF-THE-BOX USE CASES

Controlled documents and SOPs	Document learning requirement management
Deviation and NCR management	Audit management
Risk management	Course participation requirements, classroom training
Instructions and recommendations for ISO 9001:2015 audits	Training certificates
Customer and supplier management, claims and feedback	Reporting for analysis and business intelligence
Electronic signatures	Employee training and qualification records and certifications
Full audit trail as required by FDA and 'GxP'	Calendar functions
External quality documents with mandatory learning requirements	Multi-language document management for HR docs, user guides etc.

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