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.

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

-Henrik Lyder
Principal,
Bentley Instruments

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.
### M-Files QMS Features

<table>
<thead>
<tr>
<th>M-Files QMS</th>
<th>M-Files QMS for Regulated Industries</th>
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<tbody>
<tr>
<td>- For compliance with ISO 9001:2008</td>
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<td>- SOP management (templates, workflows, processes)</td>
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<td>- CAPA / NCR management</td>
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<td>- Employee training and qualification records</td>
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<td>- Quality Manual templates</td>
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<td>- Instructions and recommendations for ISO 9001:2008 audits</td>
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<td>- Audit trail to track changes in documents and records</td>
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<tr>
<td>- For compliance with regulations, such as FDA 21 CFR Part 11 and EU Annex 21</td>
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<td>- Digital and electronic signing capabilities</td>
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<td>- Full audit trail required by FDA 21 CFR Part 11</td>
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<td>- Calendar view</td>
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<td>- Reporting for analysis and business intelligence</td>
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### 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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**M-Files Deployment Options:**
- Cloud
- On-premise
- Hybrid

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**“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

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**M-Files QMS Modules:**
- Document Control
- Personnel Database
- Training Management
- Building Inventories
- Quality Assurance
- Repeating quality tasks
- Tracking Subcontractors and Suppliers

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