M-FILES FOR QUALITY MEDICAL DEVICES & DIAGNOSTICS – FREQUENTLY ASKED QUESTIONS

VERSION 1.0 | LAST UPDATED MARCH 2026

This document answers common questions about M-Files for Quality. It complements the configuration, demo flow, and setup guidance, and can be shared with customer stakeholders and internal teams.

Contents

What is M-Files for Quality - Medical Devices & Diagnostics? 2

What is different between M-Files QMS and this product? 2

What is a preconfigured reference vault? 2

What is included out of the box, and what requires implementation work? 2

What core objects and workflows are included? 3

How is Training Management configured? 3

Does the product support “Process” and “Product” anchoring for Medical Devices & Diagnostics? 3

Can a customer release a small amendment without retraining everyone? 3

What are validation requirements for the product? 4

What do customers get on day one with a new deployment? 4

How does controlled document release work at a high level? 4

How do training and learning rules work? 5

How are audits managed? 5

How are Process and Site used in day-to-day operations? 5

What is a Named ACL? 5

Do customers need to enable full audit trail, and what’s the impact? 6

What is M-Files for Quality - Medical Devices & Diagnostics?

M-Files for Quality – Medical Devices & Diagnostics is a preconfigured Quality Management System (QMS) designed for regulated organizations in the medical devices and diagnostics industry. It includes ready-made structures for quality processes, controlled documents, training management, and quality records, which can be tailored during implementation.

What is different between M-Files QMS and this product?

M-Files for Quality – Medical Devices & Diagnostics builds on the standard M-Files QMS foundation but is more preconfigured for regulated environments. It is designed to be more audit-ready out of the box, letting customers start closer to a working solution and tailor it during implementation.

Key points:

- Same foundation: metadata-driven M-Files QMS delivered as a preconfigured vault.
- More preconfigured: more audit-ready and preconfigured for Medical Devices & Diagnostics.
- Faster start: closer to out of the box readiness, with less initial configuration needed.

What is a preconfigured reference vault?

A vault is the M-Files repository that stores all content and configuration, including objects, document classes, workflows, and integrations.

In M-Files for Quality, a preconfigured reference vault provides a ready-made QMS structure that serves as a starting point for implementation. Customers use it as a baseline and tailor it to their specific processes and requirements.

What is included out of the box, and what requires implementation work?

Out of the box, customers get a working reference configuration with predefined object types, workflows and an implementation checklist. This provides a structured starting point for deploying the QMS.

Implementation work typically includes configuring users and user groups, adjusting views, defining PDF layouts, setting up master data (for example: departments, processes, and sites), and completing migration, security, backup, and validation planning.

Key points:

- Out of the box: reference configuration with predefined objects, workflows, and checklist.
- Implementation: user setup, views, layouts, master data, migration, security, backups, and validation planning.

What core objects and workflows are included?

The reference structure includes core QMS objects and workflows for managing quality processes, documents, and records. These cover key areas such as audits, issues, corrective actions (CAPA), suppliers, and controlled-document structures.

Key points:

- Core objects: Audit, Recorded Issue, CAPA, Supplier, Process, Product, and Site.
- Training-related objects: Training, Learning Rule, and Training Record.
- Controlled document structures and workflows are included.

How is Training Management configured?

Training Management is integrated with controlled content. Changes to controlled documents can automatically trigger training requirements, making sure that personnel stay up to date.

The solution includes learning rules and training records and supports capturing training evidence also for personnel who are not system users (for example, factory or temporary staff), ensuring audit-ready evidence.

Key points:

- Changes in controlled content can trigger training requirements.
- Learning rules and training records are included.
- Training evidence can be recorded for non-system users.

Does the product support "Process" and "Product" anchoring for Medical Devices & Diagnostics?

Yes. The reference configuration includes **Process** as a core object type and supports structuring QMS content around processes, departments, and sites. **Product** anchoring can be applied depending on the customer's data model and regulatory needs. This is typically defined during implementation.

Key points:

- Process is included as a first-class object type.
- Supports structuring content by process, department, and site.
- Product anchoring is configurable and defined during implementation.

Can a customer release a small amendment without retraining everyone?

By default, changes to controlled documents can trigger new training requirements. This applies to both major and minor changes to ensure compliance.

If a customer needs to allow amendments without retraining, this must be defined as part of the solution design during implementation.

Key points:

- Changes to controlled documents can trigger training requirements.
- Applies to both major and minor changes by default.
- Exceptions (no retraining) require configuration during implementation.

What are validation requirements for the product?

The product can be validated by the customer or a qualified partner. Validation is not provided as a standard packaged service by M-Files and must be agreed as part of the implementation.

For regulated environments, deployment options should be evaluated. Standard Cloud may not be suitable due to upgrade scheduling, and alternatives such as Premium Cloud with a defined schedule or self-hosted environments may be considered.

Key points:

- Validation is performed by the customer or qualified partners.
- Not included as a standard M-Files service offering.
- Deployment model should be selected to support validation requirements.

What do customers get on day one with a new deployment?

Customers start with a preconfigured QMS vault that includes ready-made structures, object types, and workflows. This enables quick piloting and early use of the solution.

The configuration is then tailored during implementation to match the customer's processes, including metadata, views, security, templates, and master data.

Key points:

- Preconfigured QMS vault available from day one.
- Includes structures and workflows for quick piloting.
- Tailored during implementation to fit customer requirements.

How does controlled document release work at a high level?

Controlled document release is managed through predefined workflows. Documents move through review and approval stages before being released as controlled versions.

Release can include server-side PDF conversion and layout handling to make sure that the output is consistent. Workflow states and approvals are configurable to match the customer's SOPs.

Key points:

- Controlled release is workflow driven.
- Includes review and approval stages before release.
- Server-side PDF conversion ensures consistent output.
- Workflows and approvals are tailored to customer SOPs.

How do training and learning rules work?

Training is managed within the QMS using learning rules and training records. Learning rules define who needs training and when, while training records capture completion and evidence.

Training can be linked to controlled documents and processes, and evidence can also be recorded for personnel who are not system users.

Key points:

- Learning rules define training requirements.
- Training records capture the completion and evidence.
- Supports training evidence for non-system users.

How are audits managed?

The solution includes objects and workflows for managing audits and audit plans. These support planning, executing, and documenting audit activities and outcomes in a controlled way.

Audit types, metadata, reporting, and permissions are configured during implementation to match the customer's internal, supplier, or customer audit processes.

Key points:

- Includes Audit and Audit Plan objects and workflows.
- Supports planning, execution, and tracking of audits.
- Tailored to customer audit processes during implementation.

How are Process and Site used in day-to-day operations?

Process and Site are structural objects used to organize QMS content and responsibilities. They support consistent classification, routing, and reporting across the system.

During implementation the customer defines these structural objects and applies their master data.

Key points:

- Organize content and responsibilities.
- Support classification, routing, and reporting.
- Defined and maintained during implementation.

What is a Named ACL?

A Named Access Control List (ACL) is a predefined set of permissions used across the QMS. It defines who can view, edit, or approve content.

Named ACLs are applied automatically, for example through workflows, ensuring consistent and controlled access without manual permission management.

Do customers need to enable full audit trail, and what's the impact?

Full audit trail is not enabled by default in the reference configuration and should be reviewed before production use. Enabling it increases the amount of event log data stored, which can impact storage and require a retention or offloading strategy.

Key points:

- Full audit not enabled by default.
- Should be reviewed before production use.
- Can increase event log data volume.