M-FILES FOR QUALITY - SOLUTION DESCRIPTION

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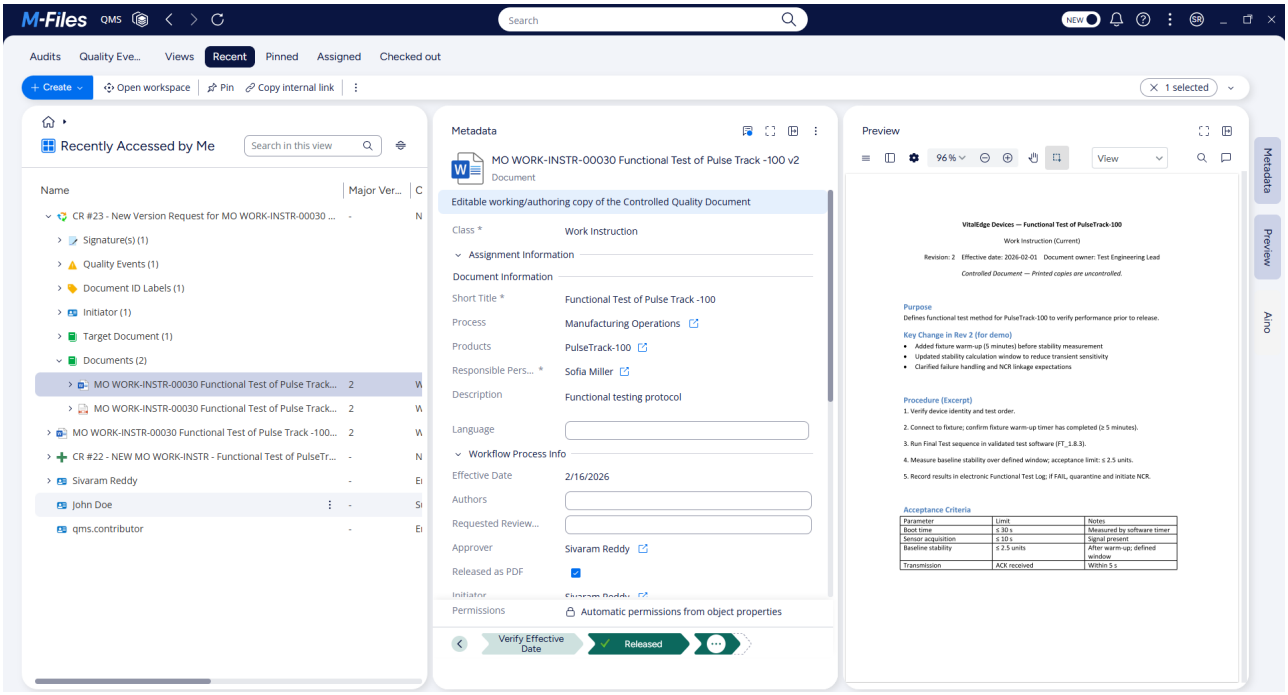
This document describes **M-Files for Quality,** a business solution for Quality Management System (QMS). It outlines the functional capabilities, technical capabilities, deployment options, and baseline requirements for getting started.



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1. Overview

1.1 Purpose

This document describes an M-Files-based Quality Management System (QMS) solution configured for **Medical Devices & Diagnostics** organizations. The solution supports controlled documentation and quality records, governed processes, traceability, approvals, and audit readiness across the product lifecycle.

1.2 Scope and Assumptions

This solution description focuses on the quality capabilities typically required to operate an audit-ready QMS, including:

- Controlled documentation and quality record management, including structures for DHF, DMR, and DHR.
- Audit management (planning, execution, findings, follow-up, and closure).
- CAPA and quality event management (for example, nonconformances, supplier issues, and complaints) with traceability.
- Supplier management, including qualification, monitoring, audits, and corrective actions.
- Risk management aligned with ISO 14971 principles, supporting risk-based decision making across QMS processes.
- Change control, including request, impact assessment, approvals, implementation, verification and validation, and closure.
- Permissions and role-based access control to support segregation of duties and audit trail expectations.
- Training management, including role- and document-driven training assignments and audit-ready training records.

The solution supports quality processes commonly required under **FDA 21 CFR Part 820, ISO 13485:2016, EU MDR/IVDR, and MDSAP**. **Compliance remains the responsibility of the customer. The solution supports compliance processes.**

Assumptions:

- The solution is implemented using standard M-Files platform capabilities together with solution-specific configuration (metadata, workflows, permissions, views, and automation).
- Integrations, reporting scope, and validation approac**h are customer-specific and confirmed during discovery.**

1.3 Intended audience

This document is intended for:

- Business stakeholders evaluating QMS capabilities and expected outcomes.
- Solution consultants and sales engineers demonstrating or piloting the solution.
- IT and administrators planning deployment, configuration, and integrations.

2. Solution at a Glance

This section provides a high-level overview of the solution, including target users, user experience principles, industry alignment, and key capability coverage.

2.1 Target Users and Operating Model

M-Files for Medical Devices & Diagnostics QMS is designed around core user roles, each with defined responsibilities in operating quality processes.

- **Quality Assurance (QA)** oversees QMS governance, document control, CAPA, and audit readiness, and is responsible for overall quality process performance.
- **Quality Control (QC)** performs inspections and testing, records results, raises nonconformances, and supports investigations.
- **Regulatory Affairs (RA)** ensures that regulated documentation and changes are reviewed from a regulatory perspective and supports inspection readiness.
- **Design and Engineering** manages design controls and technical documentation, ensuring traceability of design inputs and outputs.
- **Manufacturing and Operations** executes controlled work instructions and production records, ensuring completeness of Device History Records (DHR).
- **Supplier Quality and Procurement** manages supplier qualification, audits, performance monitoring, and supplier corrective actions.
- **Executive Management** reviews trends and key performance indicators through management review materials (audits, CAPA, supplier performance, complaints).
- **Training Coordinator or Quality Training Owner (often within QA)** manages training rules, monitors completion, and ensures training records are audit-ready (this role can be combined with QA in smaller organizations).

The operating model is **process- and record-centric.** It is anchored on two key master data dimensions:

- **Product (device, product Family, or product Line):** used to structure DHF, DMR, and DHR documentation, manage change control, and analyze quality trends.
- **Process (QMS and operational processes):** used to organize controlled documents, audits, CAPA classification, and training requirements.

Quality work is executed through controlled objects (such as documents, audits, quality events, CAPAs, changes, and training records) and related work items (reviews, approvals, and tasks). Governance is enforced through workflows,

metadata, and permissions. **Most objects are linked to Product, Process or both to ensure traceability and audit-ready retrieval.**

2.2 User Experience Model

M-Files for Medical Devices and Diagnostics QMS uses a **role- and context-driven** user experience model.

Although the solution is built on metadata, workflows, and relationships, users do not interact with these constructs directly. Instead:

- Users work through **personalized views** (for example, "My Work") and role-based views such as Documents, Quality Events, Audits, and Suppliers.
- Actions are performed in the context of **quality objects** (for example, audits, CAPAs, controlled SOPs, and change requests).
- Classification, lifecycle management, and access control are handled automatically through configured rules and workflows.

This approach reduces administrative effort while ensuring controlled execution and full traceability for audit readiness.

2.3 Industry Scope & NAICS Alignment

The solution is designed for organizations operating in regulated medical device and diagnostics environments. The following NAICS categories represent typical industry alignment.

NAICS CODE	NAICS TITLE	DESCRIPTION	RELEVANCE TO THIS QMS SOLUTION
339112	Surgical and Medical Instrument Manufacturing	Manufacturing of surgical and medical instruments and related devices.	Strong alignment with controlled documentation, DHF/DMR/DHR structures, audits, CAPA, and supplier control.
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	Manufacturing of devices such as patient monitoring and electrotherapy equipment.	Strong alignment with design controls, change management, production records, and risk-based audits.
325413	In-Vitro Diagnostic Substance Manufacturing	Manufacturing of IVD reagents and diagnostic substances.	Strong alignment with document control, supplier qualification, complaint handling, and traceability.
339113	Surgical Appliance and Supplies Manufacturing	Manufacturing of surgical appliances and supplies (as applicable).	Relevant for organizations producing consumables; supports supplier control and record retention.
334516	Analytical Laboratory Instrument Manufacturing	Manufacturing of analytical instruments used in laboratory environments.	Relevant for organizations managing analytical instruments; supports design changes and calibration evidence.

NAICS selection is customer-specific and confirmed during discovery.

2.4 QMS Capability Coverage

The following table summarizes how the solution supports key QMS capabilities.

QMS CAPABILITY	M-FILES SUPPORT	NOTES
Documentation & Record Control	✅ Strong	Metadata-driven document management, version control, and audit trails.
Quality Planning	⚠ Limited	Planning supported through workflows, document templates, and audit plan objects.
Audit Management	✅ Basic	Supports audit planning, execution, and tracking; advanced analytics may require external tools.
Training Management	⚠ Basic	Supports training assignments and records; no full learning management system (LMS) features.
CAPA & Root Cause Analysis	✅ Moderate	Supports CAPA workflows and traceability; advanced analytics may require external tools.
Quality Improvement (QI)	❌ Minimal	No native Lean or Six Sigma tools; improvement relies on external systems.
Supplier Quality Management	✅ Moderate	Supports supplier qualification, audits, and records; advanced performance tracking may require extensions.
Change Management	✅ Available	Structured change control workflows with traceability and approvals.
Risk Management	⚠ Limited	Risk handling supported through linked objects and workflows; no full ISO 14971 risk module.
Complaint Handling	✅ Moderate	Complaint records and CAPA linkage supported; no dedicated complaint management module.
Product Recall Management	❌ Not available	Not included out of the box; requires configuration.

2.5 Technical Features

The following table summarizes key technical capabilities of the solution and highlights differences compared to the previous M-Files QMS 8.0 solution.

FEATURE AREA	M-FILES SUPPORT	NOTES
Business Intelligence (BI)	❌ Not available	Requires external tools such as Power BI.
Low-Code/No-Code Workflow Builder	⚠ Basic	Supports no-code workflow configuration; effective use requires platform familiarity.
AI & Predictive Analytics	⚠ Limited	Aino provides basic assistance.
Mobile Access	✅ Available	Mobile application supported; limited for advanced shop-floor or IoT scenarios.
IoT Integration	❌ Not available	No native IoT connectivity.
Cloud Deployment	✅ Available	Supports cloud, on-premises, and hybrid deployments.
ERP/PLM Integration	✅ Available	Standard connectors available; complexity depends on external systems.
Compliance	⚠ Limited	FDA 21 CFR Part 11 compliant; granular permissions and audit trails.
OOTB Industry specific configuration	⚠ Limited (8.3 for medical devices)	Can be done but not built in.

3. Core Capabilities

Core capabilities are organized around:

- A structured **information model** that defines business objects and their relationships
- Configured **workflows** that govern lifecycle, approvals, and process execution

Together, these enable controlled, auditable, and efficient quality operations.

3.1 Information Model

M-Files for Medical Devices & Diagnostics QMS is built on a structured information model based on business objects. These objects represent **controlled documents, quality records, quality events, and governance artifacts**.

The information model provides process context, enables workflow automation, and supports role-based user experiences. It also ensures that all information is consistently classified, traceable, and accessible for audit and reporting purposes.

Product and process as core master data (Medical device criticality)
The solution uses **Product** and **Process** as foundational objects to ensure consistent classification, traceability, and audit-ready retrieval.

- **Product** is a central object that anchors Device master Record (DMR), Design History File (DHF), and Design History Record (DHR) documentation. It links documents, quality events, risk records, and changes to a specific device, product family, or product line. Typical metadata includes product name, model number, device class, intended use, and regulatory pathway. Product context is also used for change impact assessments and quality trend analysis.

- **Process** represents QMS and operational processes, such as design controls, production controls, purchasing, and CAPA. It is used to organize controlled documents, plan audits, assign training, and analyze issues by process area. **Note:** The process metadata property is a renamed version of the "MainProcesses" field from the QMS 8.0.2 baseline. The alias and data type remain unchanged.

Additional Metadata Properties

The following metadata properties extend the standard QMS 8.0.2 baseline for the MedTech configuration:

- **Serial number of product**
  Implemented as a multi-select lookup value, enabling unit-level traceability. This allows Device History Records (DHR) to be assembled based on specific serial or lot numbers from a controlled list.
- **Document category**
  Used to classify documents into functional categories such as DMR, DHF, and DHR. This enables metadata-driven document grouping and eliminates the need for separate folder structures or document classes for each record type.

Controlled documents and quality records

Controlled documents represent governed quality documentation such as quality manuals, SOPs, work instructions, forms, specifications, templates, and controlled external documents. These documents follow defined lifecycles and are linked to relevant processes, products, and owners.

Quality records represent evidence generated through quality processes. Examples include test results, audit evidence, approvals, and training records. These records are stored as managed objects and linked to relevant context such as product, process, audit, or CAPA..

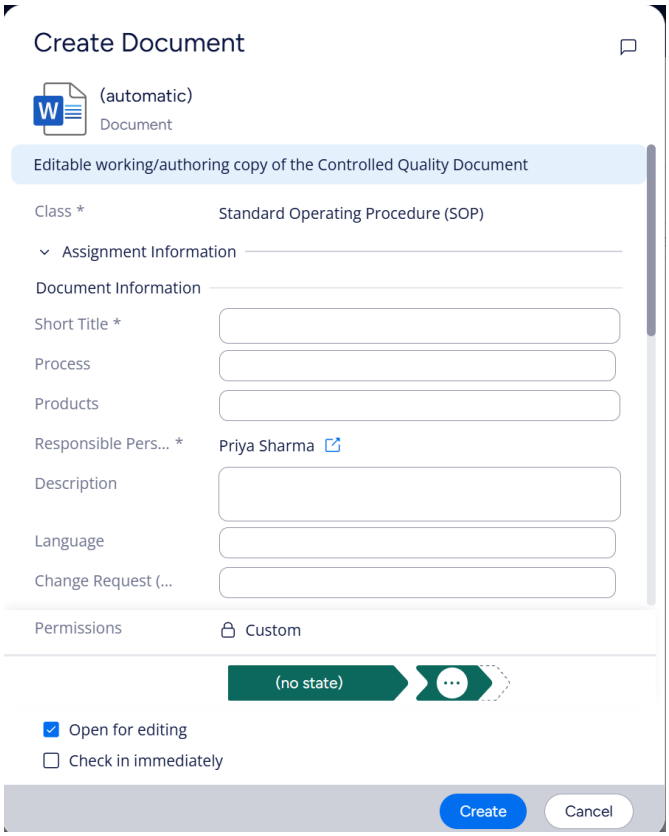
Regulatory traceability

he configuration supports document types required under ISO 13485 and FDA QMSR. Key regulatory record groupings include:

- **Device Master Record (DMR)** — defined in FDA QMSR §820.181 and ISO 13485 Clause 4.2.3
- **Device History Record (DHR)** — defined in FDA QMSR §820.184 and ISO 13485 Clause 4.2.4
- **Design History File (DHF)** — defined in FDA 21 CFR Part 820.30(j) and ISO 13485 Clause 7.3

These records are not stored as folders or separate systems. Instead, they are assembled dynamically using metadata and relationships, anchored to the Product object.

> Note: The configuration described above represents a **Tier 1 vault configuration**. DMR, DHF, and DHR are implemented as metadata-assembled document views rather than as a full design control or PLM workflow engine.
>
> Design control lifecycle workflows (such as Design Input, Design Output, Design Review, Verification and Validation, and Design Transfer as structured workflow objects) are outside the scope of the current configuration.



DHF, DMR, and DHR Context

For medical device and diagnostics organizations, DHF, DMR, and DHR collections are represented through linked objects and metadata-driven views. Three dedicated document classes are implemented in the MedTech (Med Device) configuration:

- **Device Master Record (DMR)**
  Anchored to the product model. Assembles released design output documents and production specifications for a device family. Maps to FDA QMSR §820.181 and ISO 13485 Clause 4.2.3.
- **Device History Record (DHR)**
  Anchored to both product model and serial or lot number. Captures unit- or lot-specific production records and evidence. Maps to FDA QMSR §820.184 and ISO 13485 Clause 4.2.4.
- **Design History File (DHF)**
  A virtual collection of documents linked to a product and categorized as DHF. Automatically assembled without requiring folders or container objects. Maps to FDA 21 CFR Part 820.30(j) and ISO 13485 Clause 7.3.

Document Classes and Document Category

The MedTech (Medical Device) configuration includes multiple document classes covering controlled documents, quality records, and training artifacts. This structure is not prescriptive—document classes vary by customer and are tailored during implementation.

The **Document Category** metadata property is applied to controlled document classes to classify documents into functional categories such as DMR, DHF, and DHR. This approach uses metadata tagging, consistent with the M-Files metadata-driven model.

Using Document Category eliminates the need for separate document classes for each record type and enables flexible, view-based document assembly. For example, Design and Development Plan documents are categorized using the Document Category property within existing controlled document classes, rather than through a separate document class..

Audit Context

An **Audit Plan** represents the definition of an audit program, including scope, frequency approach, and audit types. An **Audit** represents an execution instance (internal, supplier, or regulatory/inspection) and includes schedule, participants, checklists, evidence, and resulting findings.

Audit Completion Notes

Audit Completion Notes provide a summary-level closure record for an audit event. This object is distinct from individual audit finding records and captures the overall outcome and disposition of the audit.

Typical information includes audit status (closed or conditionally closed), a summary of findings, and any follow-up obligations. Audit Completion Notes complement related documents such as audit reports and finding records, and provide a single reference point for audit closure verification during subsequent reviews or inspections.

Internal Auditor Training and Competency

Lead auditors are typically independent of the audited area, in line with the independence requirements defined in ISO 19011:2018 §7.

M-Files QMS supports internal auditor training programs aligned with these competency requirements. The training module can be used to assign and track auditor qualification training, creating audit-ready records of auditor competency that can be retrieved during inspections or surveillance audits.

In the configuration, the Lead Auditor role is typically assigned read-only access to relevant audit objects during an active audit (such as audit plans, scope, findings, and evidence), without requiring full vault access. This supports auditor independence while allowing access to the necessary information for audit execution and reporting.

Findings, and CAPA Context

A **Quality Event** (for example, nonconformance, audit finding, supplier issue, or complaint) represents a controlled record of an issue requiring investigation, decision, and closure.

CAPA objects represent corrective or preventive actions linked to originating events and supporting evidence.

> **Note:** The term **Quality Events** replaces **Recorded Issues** used in earlier versions.

CAPA Verification and Validation

CAPA objects support explicit **verification** and **validation** as governed stages in the corrective and preventive action lifecycle.

- **Verification** confirms that the planned action was implemented as specified
- **Validation** confirms that the implemented action is effective in preventing recurrence

These stages are enforced as separate workflow states in the CAPA processing workflow, requiring evidence capture and approval at each step.

This approach complements the standard 365-day effectiveness re-assessment by providing near-term verification and validation at the point of closure. It supports regulatory expectations defined in FDA QMSR §820.198(e) and ISO 13485 Clause 8.5.2.

Containment

Containment is a standalone object type that captures immediate actions taken to prevent nonconforming product or material from being used, shipped, or progressing further in production.

Containment is distinct from root cause investigation and CAPA. It addresses immediate risk while the investigation continues. Typical containment actions include product hold, segregation, quarantine, and rework or sorting.

Containment objects are linked to the originating Quality Event (such as a nonconformance or supplier issue) and to the affected Product where applicable. This ensures traceability from detection through containment and final disposition.

Key metadata includes containment action type, affected product or lot, quantity affected, disposition decision, responsible person, and verification status.

As a separate object type, Containment maintains its own lifecycle independent of the originating issue. This allows containment actions to be tracked, verified, and closed on their own timeline while the parent investigation continues.

Supplier context

A supplier object represents an external provider, including classification, qualification status, quality agreements, and performance history. Supplier-related activities such as audits, issues, and corrective actions are linked to the supplier record, enabling a complete and auditable supplier quality history.

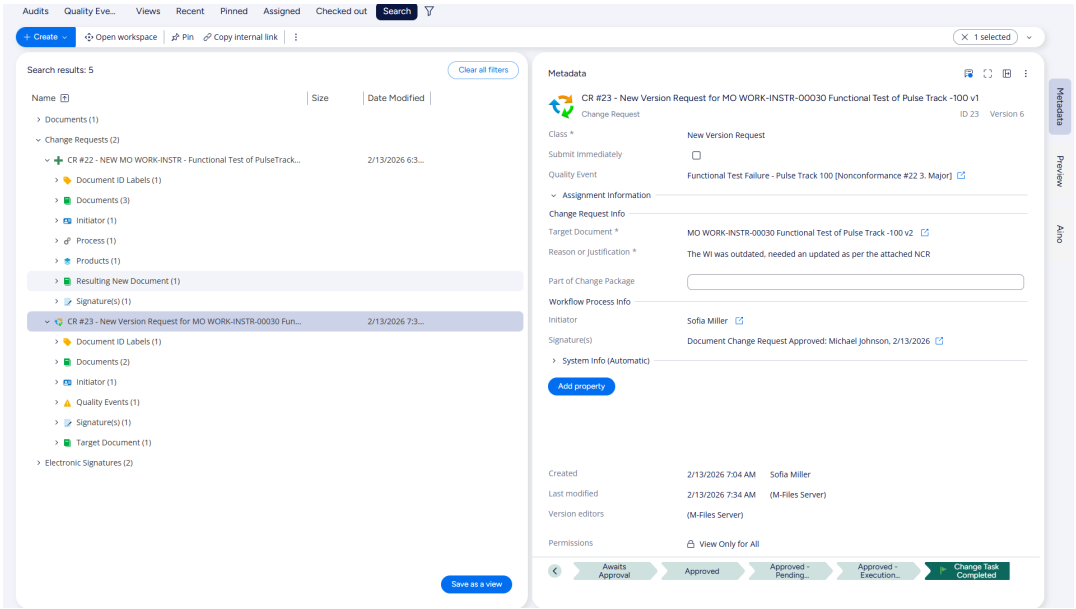
Risk management context (ISO 14971)

Risk objects support risk-based decision-making across audits, CAPA prioritization, supplier control, and change impact assessment. Basic risk scoring is supported. Advanced risk management methods (such as FMEA, FTA, or full ISO 14971 workflows) are outside the scope of the standard configuration.

Change control

Change requests represent proposed changes to controlled documentation or processes. They include impact assessment, approvals, implementation, and verification.

Change objects are linked to affected documents, training requirements, and related records to ensure full traceability.



Training management and records

Training is managed through structured objects that (1) define the training requirements and (2) capture completion evidence.

- **Learning rules** define how training is assigned (for example, based on roles, processes, or document change).
- **Training assignments** represent required training tasks with due dates and status.
- **Training records** provide auditable evidence of completion, including completion date, trainer if applicable, and supporting material).

Two document classes support the training:

- **Course Attachment** for training materials.
- **Training Event Attachment** for attendance records and assessment evidence.

Both use controlled document lifecycles to ensure proper versioning and governance.

Objects and Metadata Summary (high level)

The following table summarizes key object types in the solution.

Object type or class	Purpose	Key metadata (examples)	Workflow	Relationships	Record category
Product	Master data for product context	Product name, model, class, lifecycle	(optional) Product lifecycle	DHF/DMR/DHR, audits, CAPA, training	QMS master data
Process	Master data for process context	Process area, owner, site	(optional) Process lifecycle	Documents, audits, CAPA, training	QMS master data
Controlled Document (SOP/WI/Spec/Form)	Controlled documentation	Type, owner, process, product, effective date, review period	Document lifecycle	Change request, training	Controlled document
Quality Record	Evidence and records	Record type, product, lot/batch, date, approver	Record status	Audits, CAPA	Quality record
Audit Plan	Defines audit program	Scope, type, frequency, owners	Audit plan	Audits, processes, sites	QMS planning record

Object type or class	Purpose	Key metadata (examples)	Workflow	Relationships	Record category
Audit	Executes audit	Scope, auditors, auditees, dates	Audit workflow	Findings, evidence, CAPA	Audit record
Finding	Captures audit output	Severity, requirement, owner, due date	Finding workflow	Audit, CAPA	Quality event
Nonconformance	Tracks deviations	Product, process, severity, disposition, containment	NC workflow	CAPA, risk, DHR evidence	Quality event
CAPA	Corrective/preventive actions	Root cause, actions, effectiveness, due dates	CAPA workflow	Events, documents, training	CAPA record
Containment	Immediate control actions	Action type, affected product or lot, quantity, disposition, responsible person, verification status	Containment workflow	Events (NC/supplier issue), product, CAPA	Quality event
Supplier	Supplier master data	Classification, risk, status	Supplier status	Supplier audits, issues, CAPA	Supplier record
Supplier Audit	Supplier evaluation	Scope, criteria, results	Supplier audit	Supplier, findings, CAPA	Supplier quality record

Object type or class	Purpose	Key metadata (examples)	Workflow	Relationships	Record category
Change request	Controls changes	Type, impact areas, approvals	Change workflow	Documents, training records	Change control record
Learning rule	Defines training logic	Trigger, roles, processes, sites, due dates	(optional) Rule lifecycle	Documents, roles, training assignments	QMS governance record
Training assignment	Tracks required training	Assignee, due date, status, priority, training type	Training workflow	Document(s), training records, person, role	Training record (assignment)
Training record	Evidence of completion	Completion date, method, verifier (if applicable)	(optional) Record status	Assignments, documents, evidence attachments	Training record (evidence)

3.2 Workflows

M-Files for Medical Devices & Diagnostics QMS uses a defined set of workflows to manage lifecycle, governance, and control across documents, audits, suppliers, quality events, CAPA, risk, and change.

Workflows are not intended to be the primary interaction model for users. Instead, they operate in the background to drive system behavior, generate work items (such as reviews, approvals, and tasks), and ensure audit trails and segregation of duties.

Product and Process as workflow drivers

Across workflows, Product and Process are used to drive:

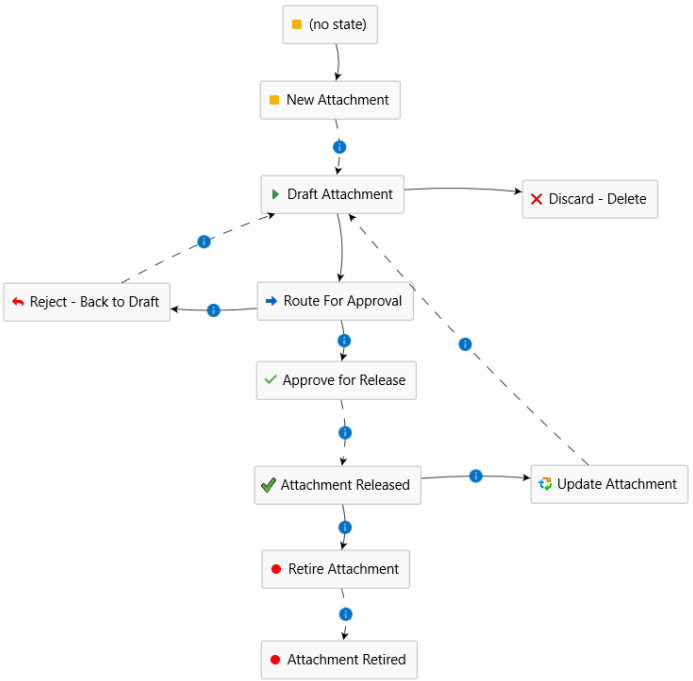
- Routing and approvals (for example, process owner review for process-related documents, or product/design owner involvement in product-related changes).
- Scope and execution (for example, audits scoped by process and optionally by product line, findings classified by process).
- Consistent classification (for example, nonconformances and CAPAs linked to product and process for reporting and trend analysis).
- Training assignment logic (for example, training rules based on process roles and controlled documents linked to that process).

Controlled document lifecycle workflow

This workflow governs the progression of controlled documents from creation to retirement.

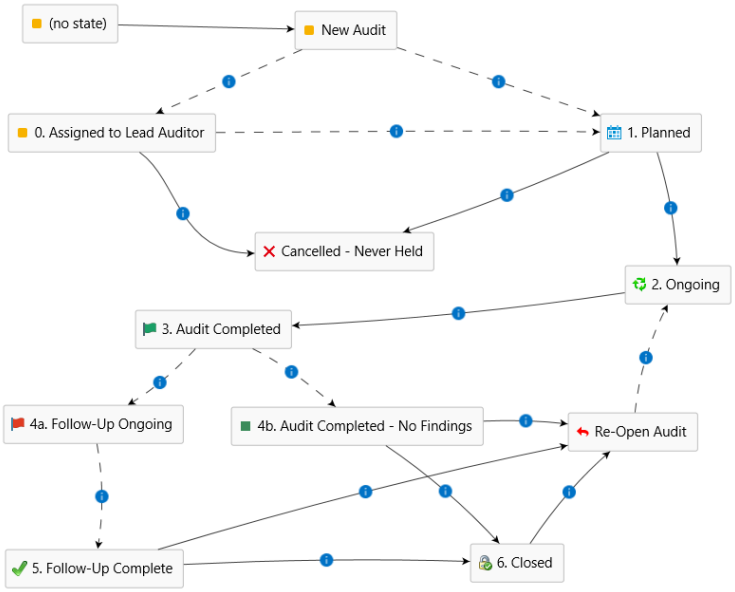
Typical states include: Draft → Review → Approval → Published/Effective → Obsolete/Retired.

The Document Category property is defined at document creation and remains consistent throughout the lifecycle. It enables classification into the DMR, DHF, or DHR contexts and supports metadata-driven document assembly without requiring additional workflow steps.



Audit finding to CAPA linkage workflow

Audit findings can trigger corrective actions and are linked to CAPA objects. This ensures traceability from requirement to evidence, finding, corrective action, and effectiveness verification.



CAPA processing workflow

This workflow governs the lifecycle of corrective and preventive actions.

Typical states include:
New → Assigned → In Progress → Completed → Verification → Validation → Closed.

The workflow extends the standard CAPA lifecycle with explicit **verification** and **validation** stages after action completion. Once the responsible person completes the planned actions (state: Completed), the workflow transitions to Verification, where implementation must be confirmed with supporting evidence.

An independent reviewer (typically a quality process manager) evaluates the evidence and either approves the CAPA or returns it for further action if requirements are not met.

Upon successful verification, the workflow progresses to Validation, where the reviewer confirms that the implemented action is effective in preventing recurrence of the issue.

In this workflow:

- **Verification** confirms that the planned action has been implemented as intended
- **Validation** confirms that the implemented action is effective in preventing recurrence

Both stages require supporting evidence, formal approval, and electronic signature before progression.

This structure provides structured, near-term verification and validation evidence at the point of closure. It complements the standard 365-day effectiveness re-assessment and supports regulatory requirements defined in FDA QMSR §820.198(e) and ISO 13485 Clause 8.5.2 for documented verification of corrective action effectiveness

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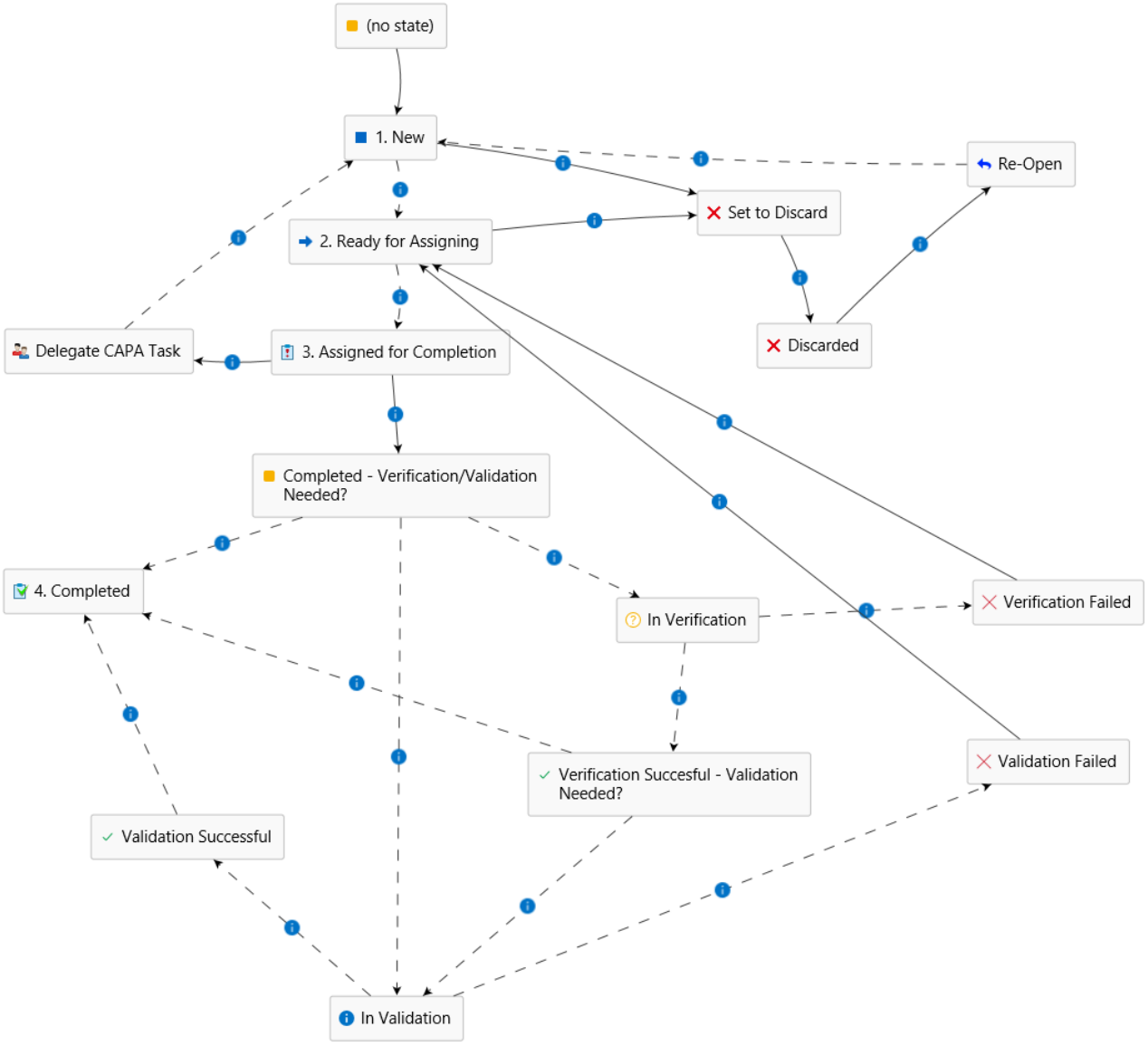
The updated CAPA Processing workflow progression is: New → Ready for Assigning → Assigned for Completion → Completed → **Verification** → **Validation** → Closed (with the existing 365-day effectiveness re-assessment cycle continuing to apply after closure).



Containment processing workflow

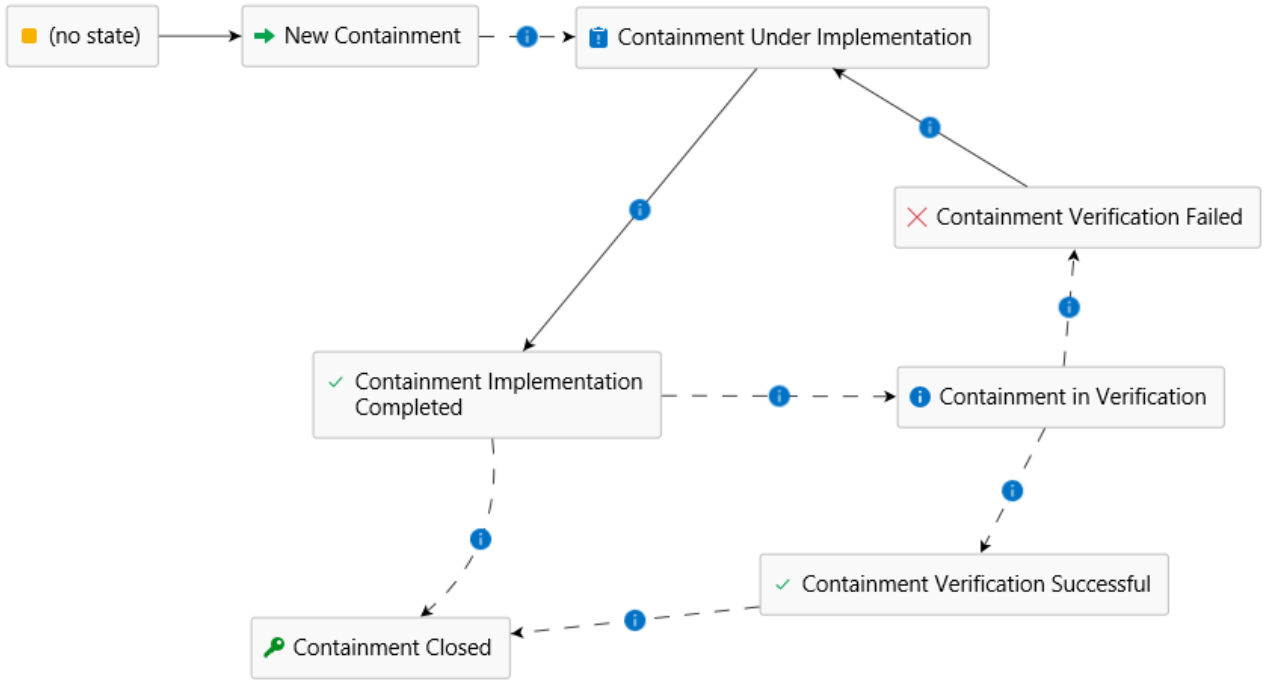
The Containment Processing workflow governs the lifecycle of immediate containment actions, from initiation through verified closure. It operates independently of the main issue or CAPA workflow, allowing containment to be managed and closed on its own timeline while the investigation continues.

Typical workflow states include: Initiated → In Progress → Executed → Verification → Closed.

At initiation, the containment record is linked to the originating quality event and the affected product or lot. The responsible person documents the containment actions taken (for example, hold, segregation, quarantine, or rework) and progresses the workflow to Executed.

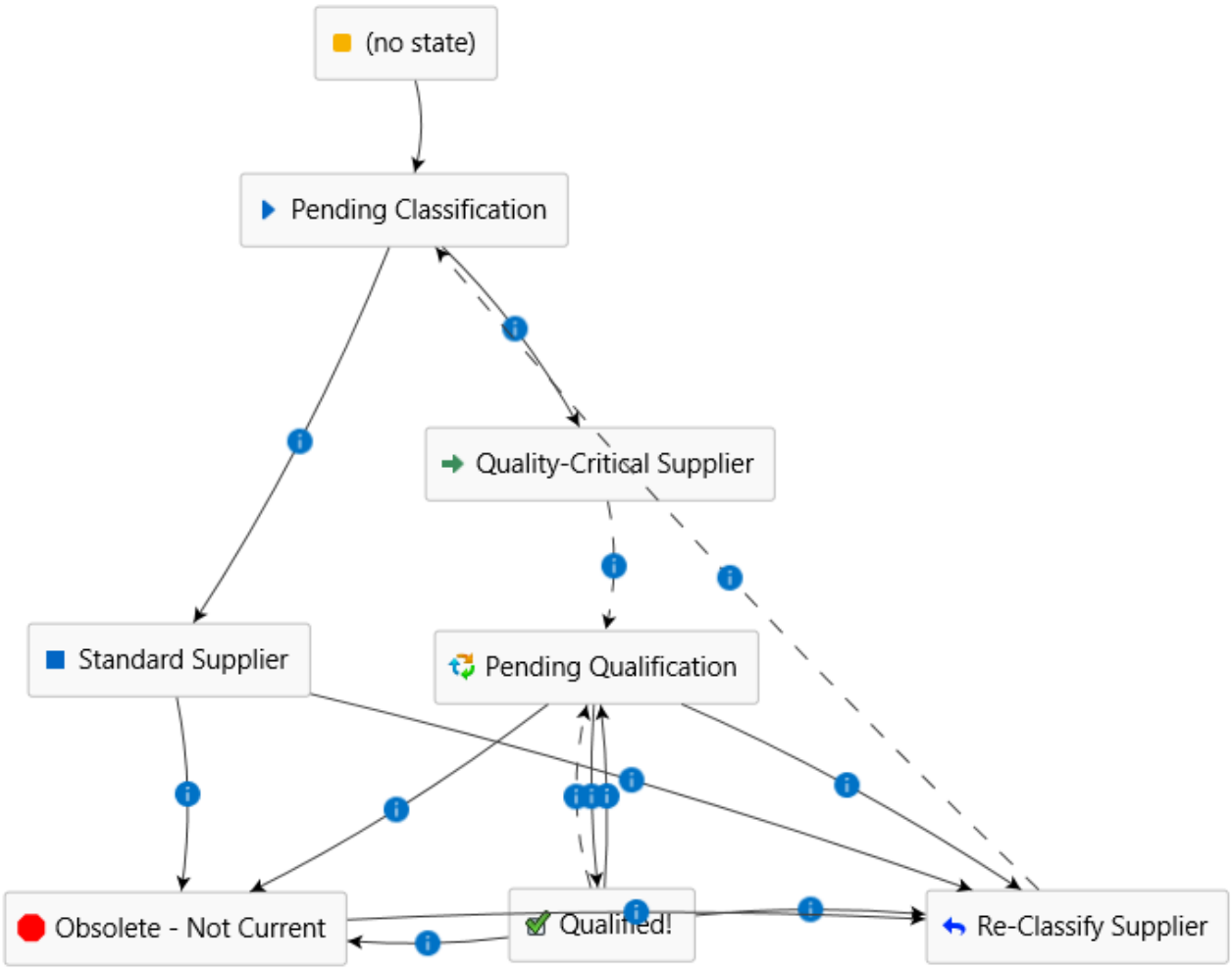
Verification is a mandatory step before closure. It is performed by an independent reviewer (typically a quality engineer or quality process manager) and confirms that all affected products or material has been properly identified, segregated, and dispositioned. The verification step captures: verification date, verifier, verification outcome (effective / not effective / partially effective), and any additional actions required. Containment is not considered closed until verification is complete, ensuring that nonconforming products do not reach the customer or re-enter production.

The workflow supports regulatory requirements for control of nonconforming products as defined in FDA QMSR §820.90 and ISO 13485 Clause 8.3.



Supplier qualification and monitoring workflow

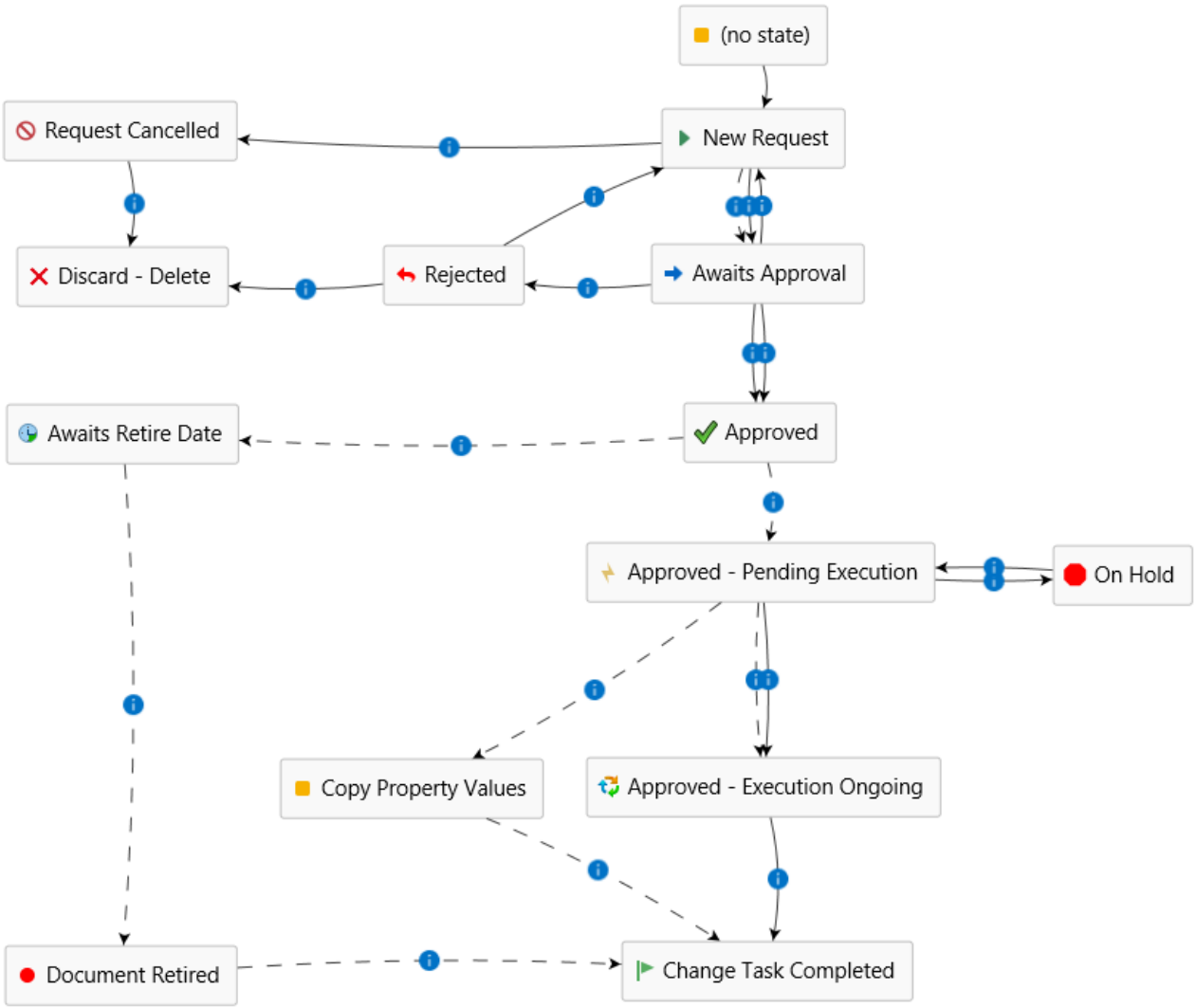
This workflow manages supplier lifecycle and status changes, such as: prospective → Qualified/Approved → Conditional → Disqualified. Supplier status is determined based on classification, audit results, performance monitoring, and supplier-related issues.



Change request control workflow

This workflow governs the lifecycle of change requests, including impact assessment, approvals, implementation, and closure.

Change requests are linked to affected documents, training requirements, and related records, ensuring full traceability of changes and their impact.



Permissions and segregation of duties (workflow-driven)

Access rights are typically determined dynamically based on workflow state and user role.

This enables controlled editing during draft or work-in-progress states, and restricted (read-only) access after approval or release. It also supports segregation of duties and audit trail requirements.

Supplier notification workflows

Suppliers do not have direct access to the M-Files vault. Supplier-related notifications within workflows are informational only and are delivered through standard notification mechanisms (such as email). No actions are assigned to suppliers within the system, and no supplier portal is required.

Training assignment and training record workflow

Training management is supported through workflows that govern assignment, completion, and record retention.

Typical states include:

- **Training Assignment**: Assigned → In Progress → Completed → Overdue (status may be derived from due date)
- **Training Record**: Draft or Collected Evidence → Verified (if applicable) → Archived

Learning rules can be used to:

- Assign training based on roles, process, product lines, and sites.

- Trigger retraining when controlled documents are updated (for example, when a major revision requires re-acknowledgement).

4. Architecture

4.1 Solution Architecture and Design Principles

M-Files QMS for Medical Devices & Diagnostics is delivered as a preconfigured M-Files vault (a "reference structure") intended for clean installations. The solution can be deployed either on-premises or as an M-Files Cloud Vault.

The reference structure provides out-of-the-box (OOTB) capabilities for core quality processes. Customer-specific configuration and extensions are expected during implementation.

The solution leverages the M-Files Compliance Kit as part of the overall configuration and licensing model (activated through a separate license).

Key design principles include:

- Vault-based **reference structure implementation**: Delivered as a full vault backup for clean installations. When restored, the vault is assigned a new vault ID.
- **Compliance Kit-driven governance**: Required Compliance Kit modules are preconfigured in the default solution. Additional modules can be enabled based on customer needs (see 4.2).
- **Controlled and auditable operations**: The solution uses M-Files versioning and metadata-driven controls to ensure that all actions and changes are traceable and audit-ready.
- **Structured master data**: Implementation includes structured objects such as Departments, Processes, and Sites to support consistent classification, filtering, and responsibility assignment across QMS documents and records.
- **Integrated training management**: The solution includes learning rules and training record management, including support for tracking training of personnel who are not system users (for example, factory or temporary wokers), supporting audit-ready training evidence retention.

4.2 Platform and Integration Dependencies

Platform prerequisites and packaged components

- M-Files Server: Requires a supported M-Files Server version compatible with the QMS solution package.
- Compliance Kit baseline: Uses M-Files Compliance Kit (separately licensed).
- Reference structure delivery: Delivered as a full vault backup for new installations.

Deployment options

- On-premises deployment: Install M-Files and restore the QMS reference vault from backup.
- Cloud deployment: Deployed as an M-Files Cloud Vault hosted in Microsoft Azure through standard provisioning.
    - Cloud operations typically include at least one administrative account with full control of vault, and managing users through the cloud subscription management tools.
    - Users connect to the vault via the cloud endpoint (no VPN required in standard deployments).

Audit trail and event logging (implementation-critical)

- The reference vault may not have full audit trail or advanced event logging enabled by default. This should be reviewed and enabled as required before production or pre-production use.

- Enabling full audit trail can significantly increase data volume and should be considered in operational planning, including retention and log management.

Compliance Kit modules and configuration constraints

The default configuration includes the Compliance Kit modules required to operate the solution. Additional modules that can be required based on customer requirements include:

- Advanced Notifications
- Event Log Exporter
- Print and Download Prevention Manager

Certain modules (such as Version Control or Change Request) may be intentionally disabled in the reference configuration, even if similar capabilities are available through other mechanisms. These modules should not be enabled without confirming the intended architecture and configuration approach..

Identity, users, and person objects

Implementations typically enable Compliance Kit user synchronization to ensure that Person objects (such as employees) are automatically created and maintained.

These objects can be enriched with additional metadata for training, responsibility assignment, and audit traceability.

Authentication sources (such as Windows domain, Azure AD, or M-Files accounts) are customer-specific and should be confirmed during discovery.

Server-side PDF processing (controlled document release and training artifacts)

Controlled document release can include server-side PDF conversion and layout processing. This PDF processing occurs on the M-Files server.

Document branding, layouts, and training certificates (if used) are configurable and customer specific.

Cloud deployments may require validation of font availability and PDF rendering as part of environment readiness checks.

Optional and customer-specific integrations

Additional integrations can be implemented based on customer requirements, for example, Digital signature integrations (such as Adobe Sign or DocuSign). These integrations are not included in the default configuration and should be defined during implementation.

5. Licensing and Deployment

M-Files for Medical Devices and Diagnostics QMS is provided as a subscription-based solution. A valid M-Files user license is required for each named user accessing the system. Licensing details, including user types and entitlements, are defined in the M-Files licensing guide.

The solution can be deployed in M-Files Cloud or in customer-managed environments depending on requirements for IT architecture, validation approach, and integration constraints.

6. Change History

The table describes the changes by document version.

VERSION	DATE	ESSENTIAL CHANGES
1.0	26.3.2026	Initial version.

7. Reference Documents

- M-Files licensing guide (customer-facing).
- M-Files QMS implementation / setup documentation (project deliverable / customer-specific).
- Customer quality system procedures governing document control, CAPA, audits, supplier controls, and change control (customer-specific / to be confirmed in discovery).
- Validation approach and deliverables (customer-specific / to be confirmed in discovery).