# M-FILES QUALITY MANAGEMENT SYSTEM

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## CHALLENGES OF MANUAL QUALITY PROCESSES

Companies face various quality requirements based on:

- need to fulfill the requirements of a quality standard, such as ISO 9001
- operating on an area which is regulated by industry specific 'good practices' or legislation
- having very quality-intensive products or services, and thus need for rigorous quality management for organizations' own internal reasons

Traditionally quality management has been conducted manually by dedicated quality personnel. The IT tools are often limited to standard office programs and email. Many quality-related documents and records require approval by handwritten signature, which traditionally has meant keeping essential documents on paper in archiving cabinets. This type of manual quality management has process issues that can over time become overwhelming, including:

- A manual quality process typically revolves around one key person, and thus poorly survives key personnel changes
- It is often difficult to get up-to-date information about the state of quality because related information and communications are scattered in an unorganized pile of paper documents, electronic files and emails. It can be almost impossible to get a quick answer to a simple question such as "have people read the new instruction we approved two weeks ago?"
- Many companies have quality policies of repeating tasks, such as weekly system health checks, periodic maintenance, monthly data recovery test, or annual SOP review. But to make things actually happen on time and according to the policy is often based on one person simply remembering to do that. Such processes tend to deteriorate over time.
- Audits, inspections and normal daily operation all produce different kinds of issues, non-conformities, audit findings or protocol deviations. Following up their corrective actions is often very tedious manual work. Quality manager can do little other than send endless email reminders about pending corrective actions.
- Quality management is document-intensive work and the sheer amount of documents grows very large over time. If the documents are kept on shared drives or simple web-based document portals, the document mass grows unmanageable.

For the aforementioned reasons many organizations are looking into implementing a dedicated quality management system, or QMS. In this paper we cover the nature of M-Files QMS, its typical use scenarios, explore the possibility of completely paperless quality management, and visit some industry-specific topics such a system validation and regulatory requirements.



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## M-FILES QMS OVERVIEW

M-Files QMS is an easy-to-use and practical tool for daily quality management. It combines in one system and one user interface

- a highly configurable database engine for any rows-and-columns type of information
- an award-winning EDMS (electronic Document Management System) for all quality-related files, electronic documents, scanned paper documents and emails

M-Files QMS is designed to be a tool for entire organization, not just quality managers. Behind its familiar looking Windows-style user interface M-Files QMS contains all the expected compliance, quality and security features such as:

- **compulsory version history** covering not just all document versions but also full history of database records, document metadata modification history, workflow changes, approvals, signings and comments
- **mandatory workflows** can be enforced to any type of document or record, enabling e.g. author-review-approve-publish-retire process for documents
- best **permissions management** on the market, combining automatic metadata driven permissions (patent pending) and group/role based permissions, covered later in this paper i.e. here
- **enforced naming conventions** allow M-Files to compose titles for selected documents and records based on their metadata
- **automatic numbering** ensuring each new document or data point has unique numeric identity according to company's numbering scheme
- **built-in electronic and digital signing** covered later in this paper i.e. here
- excellent support for **disaster recovery** both via M-Files full version history and M-Files built-in backup
- **simple and intuitive user interface** enabling high quality work with moderate training
- **support for electronic archiving** can be enabled by synchronizing all content meeting certain criteria (documents of a closed project or discontinued product) to an off-site archive
- **soft delete** hides all deleted document from sight but keeps them still in the system, allowing system administrator to recover content that was accidentally or incorrectly deleted by users, or search for lost content in case of suspected malicious use
- **full time-stamped audit trail log** of all activities, including all data/document content changes, opening documents for viewing, log-ins and log-offs, changes to user's roles or permissions and changes to metadata structure or workflows; each log item is a complete report of the event in question; complete log history can be exported to XML



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M-Files QMS contains out-of-the-box a comprehensive set of modules to cover many typical quality processes and use cases. Unlike some other systems, these modules are contained within single installable software system. If a company wishes to start by using QMS for one purpose only (only for SOPs, only for customer feedback etc.), we enable that by installing the full package but hide the currently-obsolete functionality from sight. The advantage is that when a company wishes to extend their QMS use to a new area, there is nothing new to license or install, simply enable the desired new function. Here we list all the QMS modules or predefined processes shipped with the product.

## DOCUMENT CONTROL MODULE

Document Control module is for keeping essential company documents such as SOPs (standard operating procedures), instructions, guidelines and templates. QMS Document Control module has the following functionality:

- major and minor versions with full version history and time-stamped audit trail
- effective template management
- enforced predefined naming conventions and automatic document numbering
- several signing options, including built-in digital signing
- automatic conversion of MS Office documents to PDF when finalized, with the option of computer generated signature page
- watermarking and header/footer labeling during document workflow; for example when a document is a draft or effective, it automatically says so on every page of the document
- automatic pre-configured document permissions for different workflow states; for example keep a draft visible to authors and reviewers only, but publish it automatically to all relevant parties when effective
- document lifecycle management and periodic review workflow e.g. annual document review with reminders, archiving of obsolete documents and obsolete versions
- new document request and document's change request linked to issues or audit findings

## PERSONNEL MODULE

The Personnel module keeps an up-to-date list of personnel with all necessary contact information and HR documents. Personnel module contents are highly linked to other modules i.e. they are present in Training module both as trainers and trainees, linked to audit findings and corrective actions in the Quality Assurance module, placed as responsible key people for projects, products, equipment, and so on. Personnel Module allows keeping essential personnel documents such as CV's, biographies and annual performance reviews under each person, with full version history and proper access rights. M-Files automatic permissions are especially handy for HR documents due to their often sensitive nature.



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In a typical M-Files fashion personnel module itself can be the master database of employees and subcontractor contact people, or personnel can be automatically updated from another system such as ERP system, HR system or MS Active Directory.

## TRAINING MODULE

QMS Training module is a comprehensive toolkit for managing training and document learning. Its features include:

- keep up-to-date course list and company course calendar
- author, approve and distribute all training material
- add training requirements to SOPs and other controlled documents
- make a course mandatory for personnel involved with a product, a project or a computer system
- record company training and self-learning
- once training is recorded and signed in the QMS, export printable training certificates
- record any external or past training's, including certificate documents
- training records are exportable to printable documents, viewable in audits and can be handed over to personnel when they leave the company
- through M-Files Reporting get metrics on training and self-learning, for example the average time per department of office that it takes to learn a new SOP

## INVENTORY MODULE

M-Files QMS is not just a great document collection but also a true database engine for managing various types of company inventories and database listings together with their data and documents. There are two main approaches for keeping databases or inventories within the QMS:

1. QMS itself can be the **master database**. This is often a good solution for small companies that may have such information currently in spreadsheets. Even larger companies may benefit from keeping a certain master database within the QMS. Setting up a new database together with metadata attributes and necessary end-user user interface views is a simple task and requires no programming.

2. M-Files QMS can also **integrate into existing databases**, e.g. bring products data from SAP or other ERP, personnel from HR system or Active Directory, customer projects from a finance system, and so on. With the QMS companies can keep the master data where it currently is, and just perform related quality management tasks in the QMS. Companies may also benefit from M-Files' superior document management capabilities e.g. keep the product registry in the ERP but manage product documentation in M-Files



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QMS contains out-of-the-box the following inventories or databases:

- **Product database**, listing product information, product lots, responsible personnel and all product documentation. Products can be linked to other QMS content such as Training (for product specific trainings) and QA module (for product quality deviations, customer feedback or audit findings).
- **Equipment inventory**, with essential information, location information, responsible people, repeating maintenance tasks and links to other content such as factory units.
- **Software system inventory**, listing all the computer systems in use together with their essential information, system specific manuals, document and validation content. For details of how this helps IT quality see chapter System Validation later in this paper. Keeping a software system inventory is a good practice for any company, especially larger ones, but it is also required in some industry-specific regulations such as GMP Annex 11, which says: "For critical systems an up to date system description detailing the physical and logical arrangements, data flows and interfaces with other systems or processes, any hardware and software prerequisites, and security measures should be available."

The list above is just the default set; more can be easily added during implementation and the irrelevant ones can be hidden from sight.

Every inventory item can have any number or any type of quality-related documents, each naturally with full version history and access control. One can think of each row in each database table also as a 'folder' for its own documents. Typical examples include equipment manuals, software installation or validation documents, product testing documents, equipment log files, and so on. Every QMS inventory item can be linked via metadata to training and Quality Assurance content, for e.g. product specific customer feedback or equipment specific training.

## QUALITY ASSURANCE MODULE

Quality Assurance (QA) module is all about managing exceptions from the expected quality standards. Such exceptions include product deviation, audit findings, negative customer feedback or just any issue recorded during daily operations. QA module's functionality includes:

- Manage all types audits and inspections including external audits by clients, regulatory bodies or certifying organizations, subcontractor audits (i.e. when you are auditing other companies) and internal audits. Each audit becomes a timed event in QMS calendar, with necessary documents, necessary email communications and responsible people.
- Record and manage all kinds of issues, audit findings, quality deviations and near-miss situations together with necessary information such as severity (major, minor, etc.), area of issue, description of the problem, recommended corrective action(s), and responsible people.
- Record and follow up all the corrective and preventive actions (CAPA). Each issue goes in its own processing workflow during which it is assigned to a responsible person, appears on the



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person's to-do list with a due date, an email reminder is automatically sent. Once the corrective task is done, the CAPA is closed either by responsible person, QA manager or both, depending on company policy. In its simplest form the corrective actions are recorded to the same electronic form used to record the problem. In more complex cases one issue turns into several corrective actions assigned to different people, each of them followed up separately. QA manager can easily get a report or an overview of all open CAPAs, and also view CAPA due dates on the built-in M-Files Calendar.

## REPEATING QUALITY TASKS

M-Files QMS allows managing tasks and quality checks that repeat over and over again. For many organizations this is the essence of ensuring that their quality remains high. Such repeating quality checks are also included in many industry specific quality standards, e.g. GMP and many more. Examples of such repeating tasks include e.g. weekly system health checks, monthly sampling and analysis of products, periodic testing of computer system recovery from its backups, or annual SOP review. Companies need to be able to show that such repeating quality checks described in their SOPs or quality manual are actually being conducted. Here's how this works in M-Files QMS:

- A dedicated ***Repeating Task*** is created in QMS, together with its schedule (how often repeated), responsible personnel and description of the task. Even though the same task is over time completed over and over again, it only needs to be created once.
- Through metadata periodic task is linked to other necessary QMS content. For example an annual SOP review is linked to the SOP itself, a weekly check of temperature loggers is linked to the correct cold storage units, a periodic IT system recovery test is linked to the computer system, and so on.
- According to the predefined schedule the periodic task automatically activates and places itself of responsible personnel's to-do list. An email reminder can be automatically sent.
- Responsible person performs the task in question and then closes it via workflow state change or an electronic signature. A new repeating task record is now created.
- The repeating task is now closed, until it automatically re-actives again after its preset time.
- Repeating tasks can be viewed from its related object via M-Files drill-down. For example drill-down from an SOP immediately reveals when it was last reviewed, and drill-down from a cold storage unit immediately shows when its temperature logger was last read.
- The history of all previous periodic tasks (e.g. all the previous temperature readings) can be viewed in periodic task's version history.
- All pending or overdue period tasks can be viewed in M-Files and built-in M-Files Calendar



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## SUBCONTRACTOR MODULE

Many organizations use subcontractors, quality critical suppliers and external freelancers. The organizations are ultimately responsible for their own subcontractors' quality, and thus need to extend their quality management beyond the boundaries of their own company.

M-Files QMS Subcontractor module allows keeping an up-to-date list of subcontractors, freelancers and other such 'trusted externals' and apply selected quality measures to them. This can be used for various purposes:

- link products, projects, IT systems or equipment to their suppliers
- link subcontractor audits findings to respective companies and follow up corrective actions
- put key contact people under each subcontractor company
- extend training requirements to subcontractor companies, and let them access SOPs, protocols and instructions via M-Files Web Access

## EXTENDING THE QMS TO FEATURES NOT LISTED HERE

The quality challenges and therefore the processes controlled with a QMS can vary significantly. M-Files QMS is a very flexible platform, and can be turned into a company specific during standard implementation consulting. This typically requires no computer programming at all, only configuration. Basic QMS functionality, such as M-Files award-winning electronic document management, easily configurable workflows and digital signing are available also for any new functionality created locally. If desired, we enable local key people becoming their QMS administrators, thus taking full control of their QMS to meet future needs. If you have a use case or real-life quality issue not covered in this paper, let us know, and we will let you know how M-Files QMS would meet your specific requirements.



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## PERMISSIONS MANAGEMENT: THE ISSUE OF COMPLEXITY

When it comes to access to electronic records many companies resemble medieval cities: city walls are high and heavily guarded, but once granted access inside, few doors has locks. In IT terms: once a user is inside company firewall or connected to a domain, there is wide access to data on shared drives or similar systems. The limited number of sensitive documents, such as job contracts and employee health information, are often kept in key personnel's private folders i.e. there is not even an attempt to control how they are shared.

However, larger companies and companies on regulated areas must not only protect their networks but also have in-house access controls to documents and data. Content must be shared, but in highly controlled fashion. Controlling access within the company is definitely not trivial, and policies chosen years ago can become overwhelmingly difficult to maintain when company grows. When the who-can-do-what matrix grows complex and large, it is very difficult to get a reliable answers to simple questions like "who has now access to our contracts?" or "what documents and data has this person access to?" or "who can see our patient files?". Strict access policies can also slow people down, make it difficult for people to back each other up, and force personnel to go through IT helpdesk every time they need to access something new. A common outcome of too strict and complex access policy is that employees come up with 'shadow' document methods to help their own work, such as using their email boxes as de-facto document repositories, effectively breaking any document control.

## M-FILES QMS SOLUTION

M-Files offers advanced **automatic permissions** (patent pending) which simplifies and automates permissions management. Automatic permissions mean that a document, record or piece of data in M-Files can automatically set its permissions based on its own metadata or a related object's metadata. Let us clarify through as example what this means, and why this is such a major feature. Let's assume a company has the following policy for their project documents:

1. each project must have a named project team and named responsible project manager(s)project documents must only be accessible by the project team and project managers
2. there needs to be an audit trail history of project team changes
3. mid-project team member changes must be handled so that at all times the current team only has access to all the documents
4. it must be possible to get a report or listing of all project documents that any given team member has created, modified, approved or deleted

Such a strict policy might be in use e.g. in companies that use a lot of subcontractors or freelancers, and thus need to limit the visibility of projects and project documents. Let’s now list again the requirements, this time with M-Files solution:



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| Requirement | M-Files solution |
|---|---|
| 1. each project must have a named project team | Project team members and project manager(s) are listed as project's metadata properties. This list is immediately visible to all relevant parties in M-Files. The personnel list to choose from can be maintained within M-Files or brought from another system such as Active Directory or HR system. |
| 2. project documents must only be accessible by the project team | First, project documents have project as mandatory metadata i.e. each document knows which project it belongs to. Secondly, project documents have their permissions derived automatically from project's team member list. Result: when saving new documents to M-Files their permissions are automatically and immediately set correctly. |
| 3. there needs to be an audit trail history of project team changes | Project's own version history reveals all current and previous members of project team. History also reveals when and by whom personnel were placed on and off the project. |
| 4. mid-project team member changes must be handled so that at all times the current team only has access to all the documents | New person is added to the project team by modifying the project's member list. As a result, all the project's documents are instantly and automatically accessible by the new team member. The opposite case is the same: when a person leaves in mid-project, he/she is only removed from project team list, and as result instantly loses access to project documents. These modifications happen automatically without any change to the documents, or any operation done by IT administration; hence the name ***automatic permissions***. |
| 5. it must be possible to list all project documents that any given team member (current or past member) has created, modified or deleted | Basic built-in functionality: a simple M-Files view or search will reveal full list with timestamps, and is exportable to a report file. |

The above example aims to give an idea on how M-Files metadata-driven permissions will allow automation of company's permission policy: ***all the project manager needs to do is keep project team list up to date, and rest assured that all the project documents are accessible by the project team and no one else***. If desired these project-specific automatic permissions can also be combined with more traditional group/role based access such as "Quality Assurance personnel automatically have read access to all documents". Automatic permissions enable organizations to let key people and content owners manage themselves the access without going through IT support every time. M-Files also makes it trivial to see what the access permissions currently are. Automatic permissions can be used in unlimited ways, for example making employment documents visible only to HR department, employee himself/herself and employee's line manager. The possibilities are endless.

Almost any document management system or even a basic network drive will allow managing document permissions to a very detailed level. However, only M-Files will make it automatic, systematically repeatable and hassle free.



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## APPROVAL BY SIGNING: CAN WE GO PAPERLESS?

Normally documents and files are kept in digital domain within a document repository, shared drive or web-based document portal. But when it is time to approve or authorize the document, the document is often printed, signed with pen, and thus starts a new life as a signed paper original. The need for handwritten signature still keeps companies stuck with paper processes.

Traditional handwritten signature has its virtues, too: it is legally binding anywhere, everyone has skills to sign, and psychologically it 'just feels right'. But signing with pen does have serious process issues including waste of time, lack of document control, constant need to ship papers between company offices, and the risk of losing the signed originals due to a document disaster. For these reasons many companies are now looking for digital signing. But that has issues as well: there is no universally approved way of applying them, digital signing always requires some sort of IT system and skills to use it, and related legislation or regulations are often vague and require too much interpretation. As a result many companies still hesitate in adopting digital signing, while other companies have come up with policies of approving electronically only less significant records, but keep documents with serious financial or legal impact still on paper.

### M-FILES QMS SIGNING OPTIONS

To cope with various requirements, including changing future requirements, M-Files QMS supports three different signing options, covered here:

#### QMS BUILT-IN DIGITAL SIGNING

M-Files QMS contains simple and effective built-in digital document signing. M-Files QMS built-in digital signatures are designed to be ***valid within the company*** i.e. they are not designed for signing contracts between two companies or other legal entities. Making this limitation makes signing simple and easily configurable. However, built-in digital signing can be extended to freelancers, subcontractors, board members and other such 'trusted externals'. Typical uses of such within-the-company signing in regulated environments include:

- company SOPs, instructions and guidelines
- training certificated and self-learning forms
- HR documents such as CVs, job descriptions and annual performance reviews
- periodic maintenance tasks, quality checks and change logs
- approval of requests, such as authorizing access to an IT system or key to company premises
- closing corrective actions based on deviations or audit findings
- several industry-specific document types, such as monitoring reports for clinical trials

Built-in digital signing's features include:



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- completely built-in: no 3rd party software or service is needed, apart from digital signing certificate which typically is acquired from any trusted provider
- signing is based on MS Active Directory Kerberos authentication, thus optionally supporting any type of authentication available for Windows domain
- companies may choose whether the daily Windows password is also their signing password, or whether separate credentials are used for signing in the QMS
- several signatures can be applied on any document or record with each signature having its own purpose, signing manifestation and legal implication presented to the signer during signing, and rendered to the document
- a document signing is initiated simply by one button click, after which user is presented with signing manifestation pop-up window with a place for signature password
- a document that awaits signing is placed on signer's to-do list, and an email reminder can be automatically generated
- MS Office documents are automatically converted to PDF documents on M-Files server once all signatures are captured
- during Office-to-PDF conversion signing certificate is embedded to the document, and all necessary signing information is rendered to the document, including a computer-generated signing page
- signed documents can be sent or submitted anywhere, and receiver can verify each document's authenticity using standard PDF viewer e.g. Adobe Reader
- complies with known standards such as FDA 21 CFR Part 11 and GMP Annex 11 (2011)

Benefits of QMS built-in digital signing over handwritten signing include:

- save time
    - avoid sending originals via mail between offices as everyone can digitally sign online
    - no more time consuming and document-blurring print-sign-scan
    - find necessary signed original document in seconds from the shared repository
- quality and compliance
    - signing timestamps cannot be forged
    - only allow the authorized personnel to sign
    - better reading quality, including the computer-generated signature page
    - use the one digitally signed original all the time for all purposes; no outdated versions lying around, and no lost paper originals because somebody borrowed it to take a photocopy but never returned



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- avoid the weak process of keeping all the 'official' documents as signed paper originals but also scanning everything to a 'shadow' electronic document collection; eventually the two document collections are destined to go out of sync

- disaster recovery and business continuity
  - through standard backup or data replication keep digitally signed originals simultaneously in several redundant storage systems or physical locations

## SIGNING VIA EXTERNAL 3RD PARTY DIGITAL SIGNING SERVICES

M-Files supports signing via known 3rd party identity management and digital signing service providers. We currently have clients using CoSign and Signom signing services, but integrating other providers is both doable and most likely rather straightforward. The implementation varies from case to case, but M-Files clients should be able to use whatever signing provider they wish. Ask us for details.

## TRADITIONAL HANDWRITTEN SIGNING

M-Files allows capturing handwritten signatures in document approval workflows. In a typical scenario an electronic document is content-approved in a workflow, then printed, signed and scanned. Next, using built-in features, the scanned image or PDF file is brought to document repository as document's latest and final version. There is now just one document (the signed original) but the final electronic version is also stored in its version history. This fulfills e.g. FDA recommendation as it links the electronic and signed versions permanently together, and prevents any modifications to the electronic document once it has been signed.

When the paper original is scanned in this fashion and necessary quality checks are done to ensure high scanning quality and no lost pages, the physical paper original may in some cases even be destroyed i.e. the scanned image now is 'the signed original'. This is obviously up to each company to decide.

Since handwritten signing involves scanning, M-Files excellent scanner support is worth mentioning. We enable scanning directly into document repository instead of saving the document first to a temporary hard drive location (often with an obscure numeric filename given by scanner). Big network scanners, local USB-connected desktop scanners and scanners connected vie dedicated scanning driver interfaces (e.g. TWAIN) are supported. During saving from scanner the document can be conveniently renamed or may receive its new title from its metadata, depending on the type of document.



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## BREAKING THE LIMITATIONS OF WEB-BASED-ONLY

Many quality management and document systems are web-based i.e. users log in via standard web browser. Being web-based is often heavily advertised and promoted as the superior way to run quality management or document management. Naturally M-Files QMS can also be used via web simply by enabling M-Files Web Access on the server (standard feature), but M-Files also offers two other connection modes which in many cases are by far superior: M-Files Client and M-Files Mobile. In fact, we consider **being web-based-only is not an advantage at all but a significant limitation**. Here's why:

- Quality management is very document-intensive work, and moving big files back and forth via web protocols is slow.
- For security reasons a web application always runs in a 'sandbox' within user's personal computer i.e. it cannot directly access local resources such as hard drives. This lack of integration slows down the work in many ways. For example, it is not possible to save a new document via normal 'Save as…', or scan a signed paper document directly into a web-based system. Instead user needs to first save it to e.g. Desktop, and then upload the document to the web application, consuming extra time and leaving obsolete files lying around.
- Web-based system will not allow working on your documents off-line. Some systems claim to have such capabilities, but they always require separate add-on software to be installed on everybody's pc, breaking the whole web-based paradigm.
- Companies using web-based applications always are in risk of having issues with different web browsers and ever changing browser versions. There are companies that are, for example, still forced to run the clumsy and unsecure Internet Explorer 6 because of their business critical web application. Software vendors may claim that their software is compatible with all web browsers, including future ones, but such claims call for healthy skepticism.

M-Files QMS offers three independent ways for users to connect:

- In-house daily users will greatly benefit from **M-Files Client** running locally on their Windows pc. Client access provides deep Windows integration, MS Office integration, instant save to QMS from any application or scanner, drag & drop save of emails within MS Outlook, unmatched speed and performance, and off-line use without network connection. Installation of M-Files Client software can be automated from standard Windows domain to all company Windows pc's and laptops.
- Standard web connectivity is enabled via **M-Files Web Access**. This is often handy for read-only type of lightweight use, such as people reading SOPs or project material, auditors reviewing product documents remotely, or employees using their home pc for quick document access. Network traffic is based on standard http/https + Java, so all standard web browsers should work, including Internet Explorer, Firefox, Chrome, Safari and Opera. The end user experience is carefully designed to be similar to the M-Files Client. Web Access is also currently the only supported mode of connection for Apple Mac users.



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- **M-Files Mobile** allows QMS connection via touchscreen smartphones. This allows finding information or approving content when a standard laptop is clumsy, such as factory environments, employees operating vehicles or during travel. Supported phones include Apple iPhone, Android, Nokia Symbian and Blackberry. M-Files mobile also works nicely on iPad and other tablets.

M-Files QMS is the only QMS on the market that supports all three connection modes, giving superior usability over every web-browser-only solution. We see this repeatedly in demos and pilot projects: even though M-Files Web Access is appreciated for certain use cases (typically reading content only), anyone who gets to use M-Files Client for 15 minutes will never go back to clumsy web login as long as client is available.



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# M-FILES QMS AS A TOOL FOR COMPUTER SYSTEM VALIDATION

In this chapter we cover how QMS can help keeping all critical IT systems in their trusted, validated state. We also cover validation of the M-Files QMS system itself.

## WHY VALIDATE AN IT SYSTEM?

Wikipedia defines validation like this: "*Validation is the process of checking that a product, service, or system meets specifications and that it fulfills its intended purpose. These are critical components of a quality management system such as ISO 9000*"

Validation can be resource-intensive work so companies should justify allocating those resources and costs. In fact, in surprisingly large companies IT systems never get properly validated or tested in any way. In some companies operating in a regulated area validation is seen as a formality, with the only goal being producing a pile of documentation to please auditors and inspectors. When such companies only attempt to 'get the paperwork done' they consciously or unconsciously allow risks to lure in their IT systems and processes. Such companies also often fail to do any change control for the system which often leads to system quality deterioration over time. They may e.g. apply significant changes to the system or the underlying IT infrastructure without any documented proof that system behaves the same after these changes. This can be a disaster in waiting.

Other companies with proper skills, resources and upper management commitment to IT quality can truly benefit from validation efforts. They may e.g. discover hidden system issues before going to production use. Ideally validation should not be seen as an 'annoying must-have' but a productive thing that is worth investing resources into.

## WHAT COMPUTER SYSTEMS NEED TO BE VALIDATED AND HOW?

Regardless of the industry companies should make justified decisions about which of their computer systems need to be tested or validated, how the validation is conducted, what documentation is produced, and how the system is kept in its trusted validated state during production. This is often far from trivial. Several industry-specific regulations require system validation, but reveal little about how it should be conducted. Prime examples of such regulations are *FDA 21 CFR Part 11* and *GMP Annex 11: Computerised Systems*, widely used in pharmaceutical industry and other life science businesses. Typically a collection of best practices emerge in the industry about the expected depth of validation. It is also somewhat unclear what systems can be trusted without any validation at all. For example many companies perform surprisingly critical operations using spreadsheets but do not even attempt to validate their use of MS Excel.

**Risk analysis** is widely recommended for making justified decisions on what to validate and the depth and focus of each validation effort. Risk analysis is a big topic nowadays so we only touch the very basics here. In a risk analysis all the adverse scenarios, including the very unlikely ones, are considered and written down, together with their impact on safety, timelines, financial loss, regulatory compliance, business continuity or reputation damage. This is again far from trivial simply because



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often the very nature of a disaster is that no one thought about it in advance. If the risk in question was known it may have even been prevented. However, when conducted carefully and by professional people, risk analysis will help in both preventing and recovering from risk scenarios with measures such as rebuilding IT infra, recovering from unforeseen key personnel changes, quickly notifying all relevant parties of serious production deviations, and more. Risks analysis can also be used as a valid tool to justify why some software systems are not validated at all.

In all cases we recommend that company keeps a list of all IT systems and through some simple and suitable system assessment writes down the justification for not validating the system. This can easily be accomplished with M-Files QMS.

## WHAT ABOUT DQ-IQ-OQ-PQ?

This acronym refers to a common validation practice of Design Qualification (sometimes Development Qualification), Installation Qualification (sometimes Implementation Qualification), Operational Qualification, and Performance Qualification. This validation approach derives from the world of manufacturing and equipment. It typically relates to a computer system when a machine, equipment or manufacturing process is computer controlled. Typical for such systems is that the purpose of the system and the performance criteria it needs to meet are well known.

DQ-IQ-OQ-PQ is sometimes seems as the way to validate computer systems such as document management systems. However, we do not recommend this validation practice for QMS. This practice simply does not work very well for general purpose server software systems used by a large number of people to perform a wide variety of tasks, including all kinds of ad hoc searches etc. However, if it is a company policy that computer systems go through DQ-IQ-OQ-PQ then they may want to consider something like this:

- DQ is defined as all the modifications of the base product locally i.e. all the configuration and local scripting done to make M-Files QMS company specific. Especially workflow settings, permissions settings, automatic data validation checks and connections to other IT systems need to be tested during DQ.
- IQ checklist is filled and signed during installation by system provider
- OQ is defined as demonstrating that system meets company process requirements, as defined in SOPs or other such documents. OQ can take many forms, including testing against written system requirements or a UAT (User Acceptance Tests) to verify that end users can repeatedly produce expected results.
- PQ is executed during pilot phase, and company may run necessary stress test to verify that system meets their requirements.

## M-FILES QMS AS A TOOL FOR COMPUTER SYSTEM QUALITY

M-Files QMS can be a really useful tool for validating all computer systems and keeping them in their validated state. Here's how:



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- QMS can act as a **central inventory of all computer systems in use**. This is much better practice than keeping the system list in a spreadsheet or home-grown database, because QMS allows storing all types of documents and other content (listed below) with each system, and will keep a full version history of each computer system separately. This gives an instant overview of all systems used across departments, functions or subsidiaries; especially useful for larger companies. This also meets known regulatory requirements e.g. GMP Annex 11 (2011) says: " An up to date listing of all relevant computer systems and their GMP functionality (inventory) should be available."
- QMS **links all software systems to their providers**, including software vendors, consulting companies and support providers. The provider companies and key people are stored in QMS Subcontractor Module, and linked to computer systems via metadata.
- To make an educated and justified decision about whether a system needs to be validated or not, QMS provides an electronic **System Assessment form**. The form can easily be tailored for each company. Once the form is filled is can be signed with an electronic signature, and stored under the computer system in question in the QMS.
- QMS is the central repository of all **computer system documents and files**, including:
    - all documentation provided by software vendor, including installation media itself
    - all files and documents created during installation
    - system-related contracts
    - system configurations data files, license keys, database export files or even complete server images
    - system validation documents, developed and signed within QMS
    - user manuals and training material
- QMS Training module can be used to schedule **computer system trainings** and provide **training certificates** for participants
- QMS will automate **repeating maintenance** of computer systems. This is a good practice in any high quality environment, but also required by certain regulations, such as GMP Annex 11 which says: "Computerised systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP." Repeating tasks may include for example:
    - monthly disaster recovery drill from off-site backups
    - weekly check of the server computer beneath the system
    - annual review of system's documentation and users' training status
- **Deviations, issues or audit findings** can be linked to their respective computer system, and followed up via the functionality of the Quality Assurance module.



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## SHOULD M-FILES QMS ITSELF BE VALIDATED?

There's no such thing as 'validated system out of the box'. Validation is never just about a software product, but it's one implementation, used for known purposes, and by trained people. Validating QMS system is relevant to some clients but definitely not all. This assessment is up to each client to decide, but we may be able to help companies in making justified decisions. For example, in some industries electronic records can replace signed paper originals only when the system storing the records is validated, potentially calling for QMS validation.

Because M-Files QMS software is designed to meet several known regulatory requirements validation should be rather straightforward. To further help this, we now offer a **QMS validation document package**. This collection pre-filled document templates aim to serve as a starting point for validation especially for smaller companies that do not have their own fully defined validation policies. The package includes drafts for validation plan, User Requirement Specification, test scripts and validation report. There are also pre-filled compliance statement for 21 CFR Part 11 and GMP Annex 11 (2011) listing each requirement and how QMS meets them. These documents are pre-filled for those requirements that are met by the software itself, while the rest is left for client to fill based on their local implementation. The package consists of MS Word documents, is in English only, and is purchased separately.

## RECOMMENDED VALIDATION BEST PRACTICES

Ultimately every company is responsible for making their own validation policy and making sure it is being followed. Here we present some ideas that often work using the QMS:

| Requirement | Typical response | Using M-Files QMS |
|---|---|---|
| company has defined the processes in which the system is to be used | dedicated SOPs should cover system use | manage SOPs in QMS Document Control module and link them to each system via metadata |
| system requirements are documented | a written URS or FRS (user/functional requirements specification) approved by quality manager or system owner | store and version-track validation documents with QMS and link to their respective system for easy retrieval |
| there is proof that local production implementation of the system meets those requirements | testing conducted during validation project and recorded in test script documents; special emphasis needs to be placed on local configuration settings | see above |
| there is a named system owner | recorded in validation plan for each system | store key personnel into QMS Computer System Database Module as system metadata |
| users are trained to use the system | Necessary courses, SOPs and instructions exist, and people have training certificates for them | Use QMS Training Module for course calendar and instruction documents, store all course material, digitally sign raining certificates and self learning forms |



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| Requirement | Typical response | Using M-Files QMS |
|---|---|---|
| login users and signers must be known, and controls must exist against using other employee's login or signing credentials | company needs an access control process, typically in a dedicated SOP | QMS can keep the SOP and process electronic system access authorization forms workflows |
| there is a periodic system review or health check process | covered in an IT SOP | use QMS periodic task functionality for this, and sign executed tasks with eSignature |
| once validated, system has change control | covered in validation SOP or similar | each system's change control log included in QMS Computer System Database |
| system and its data are backed up | backup is covered in SOPs or other such instructions | use M-Files QMS internal backup for daily backup, including off-site (obs. note that QMS itself allows recovery of lost, corrupted or deleted files, so backups are only needed for Disaster Recovery) |
| there is adequate proof that system can be fully restored from its backups | recovery and periodic testing are covered in SOPs | use QMS **periodic tasks** for notifying and recording regular restore testing of all systems |



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## SPECIAL REQUIREMENTS OF ULTRA SECURE ENVIRONMENTS

Some environment require 'Swiss Bank security' or run 'close to paranoid' security schemes where they attempt to protect the company against force majeure disasters, acts of terrorism or crime, or a malicious in-house IT administrator. Typically such environments, such as defense contractors, finance companies or governmental bodies, also have the resources to execute such strict controls. For these environments M-Files can implement following custom solutions:

- strong authentication with password + RSA dongle, used for login and digital signing
- live replication of production document vault to redundant data centers
- live replication of entire system contents or at least system logs to an external, independent 3rd party location, not controlled or accessible at all by company's own IT administration



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# M-FILES QMS SYSTEM REQUIREMENTS

## ON-PREMISES SERVER AND CLIENT

M-Files is compatible with both 32-bit and 64-bit Microsoft Windows operating systems. The 32-bit and 64-bit systems have separate installation programs.

The M-Files software can be installed in computers running on one of the following operating systems:

- Windows Server 2008 R2
- Windows Server 2008
- Windows Server 2003 Service Pack 1 or later
- Windows 7
- Windows Vista
- Windows XP Service Pack 2 or later

## M-FILES CLOUD VAULT

QMS can be hosted via M-Files Cloud Vault, based on the robust Microsoft Azure cloud service. Depending on the requirements the cloud-based QMS can either trust client's existing Windows domain, or be totally separate from client's other IT environment.

## M-FILES MOBILE

Supported devices include Apple iPhone and iPad, Android phones and pads, Nokia Symbian and Blackberry.



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## SYSTEM LICENSING

QMS has simple annual licensing scheme, depending on the personnel size of the company. We consider M-Files QMS being the most affordable true QMS with anything close to the set of functionality and modules provided. Contact us for details or a quote.

## HOW TO GET MORE INFORMATION OR TEST M-FILES QMS

The list of M-Files QMS modules, functionality and features can be a bit overwhelming at first. Typically companies looking for a QMS are looking for a simple solution to one or two known issues, instead of implementing every module or exploiting every M-Files QMS feature. What we recommend is the following:

- If you have a use case or an urgent issue, and wish to know if and how M-Files QMS would help you solving it, simply contact us via email at qms@m-files.com or contact your local M-Files partner or account manager.
- If you wish to test M-Files QMS locally we can run a local pilot for you. Instead of just sending the link to a downloadable software package we prefer to do a short (from half a day to two days) workshop where we look at your use case or issue, instantly fine tune the QMS to your process, and then leave it running for a 60 day period. Even though such a workshop is billable work, the outcome most likely better for all parties. We also wish to demonstrate how easily configurable M-Files QMS really is. In its simplest form a standard Windows pc (e.g. quality manager's own laptop) can act as your QMS demo environment, hosting both M-Files server and client.



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