M-Files® QMS
The agile compliance platform for regulated Industries
Digital Documents
M-Files®

QUICK FACTS

2005
entered ECM market

400+
employees

600+
resellers

8000+
customers

OFFICES IN

finland

united states

united kingdom

france

germany

australia

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ABM COMPOSITE
Arctic Biomaterials

Medix
Biochemica

Abbott
A Promise for Life

NordLab

valon
multispot laser

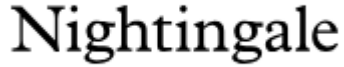
CENTILLION
ELECTRONICS

FinVector
Vision - Therapies

muRata
INNOVATOR IN ELECTRONICS

ECHOSENS
The liver company

bioretec


Nightingale

Ambu
Ideas that work for life

GETINGE

ORIFARM

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What the market ANALYSTS say

Gartner

Visionary

Magic Quadrant for ECM

2017

Gartner

FORRESTER®

Leader

The Forrester Wave:

ECM Business Content

Services

2017

Forrester Reseach

NUCLEUS RESEARCH

Leader

ECM Value Matrix

2017

Nucleus Research

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THE NATURE OF IT SYSTEMS IN REGULATED INDUSTRIES

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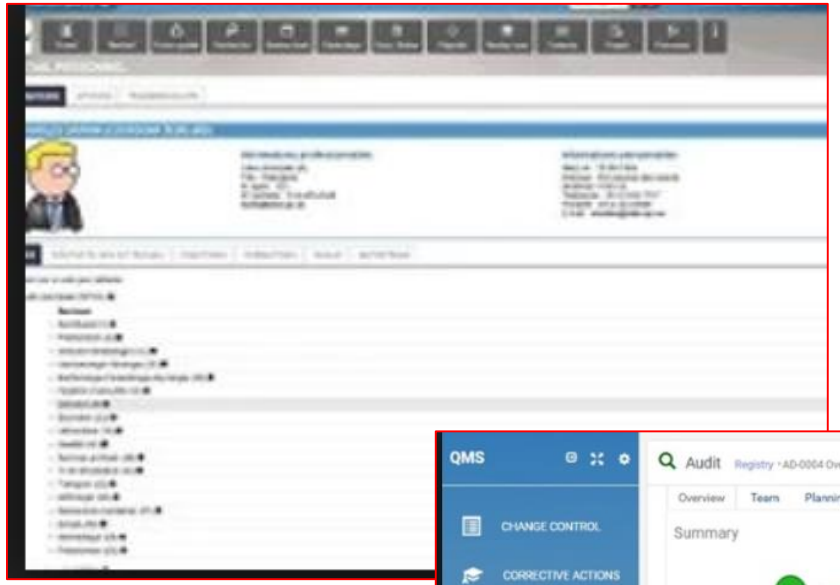
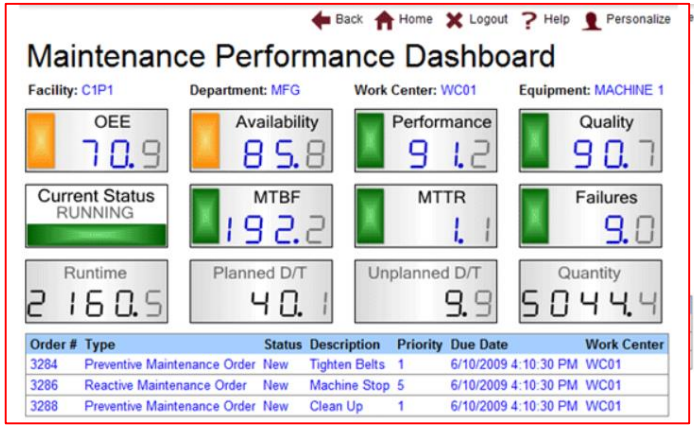
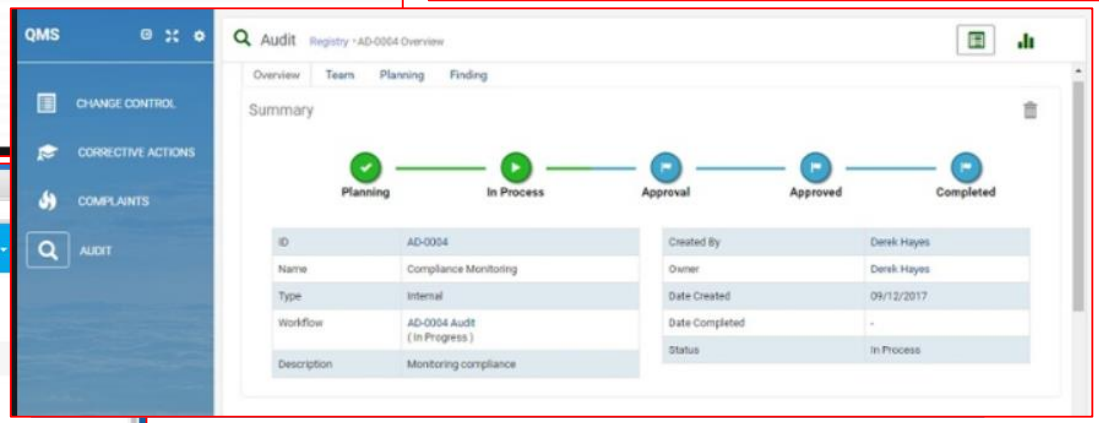
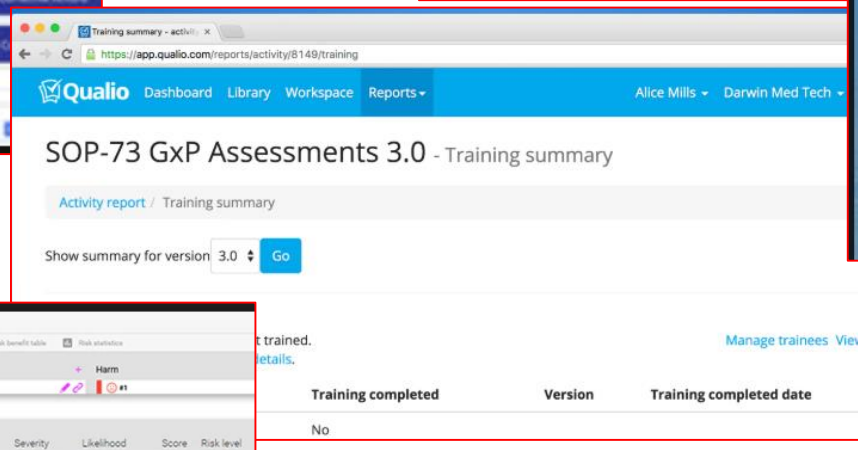
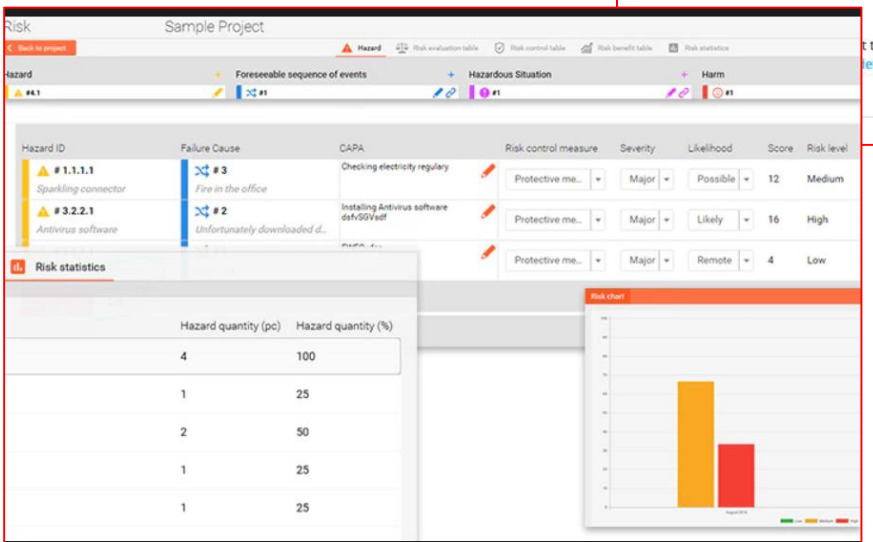
So many systems!

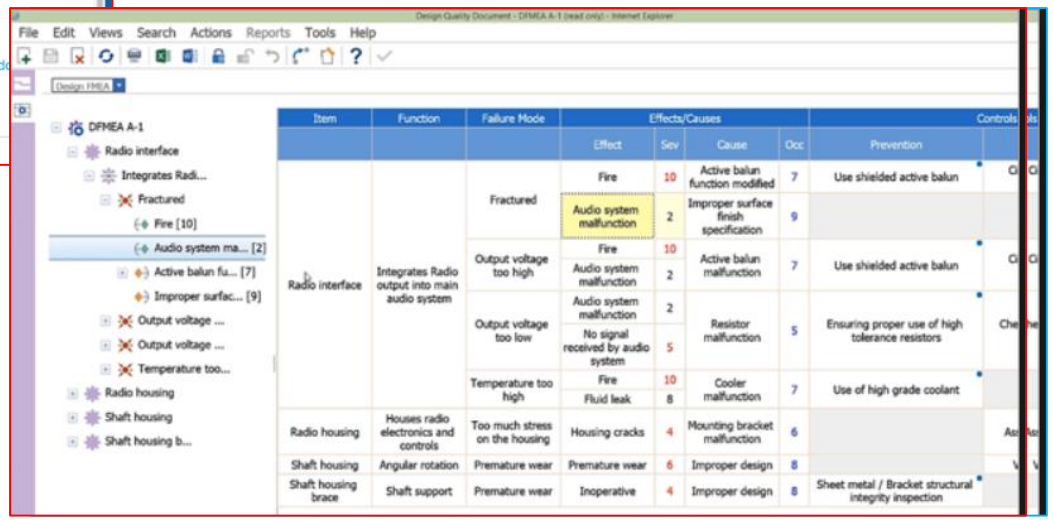






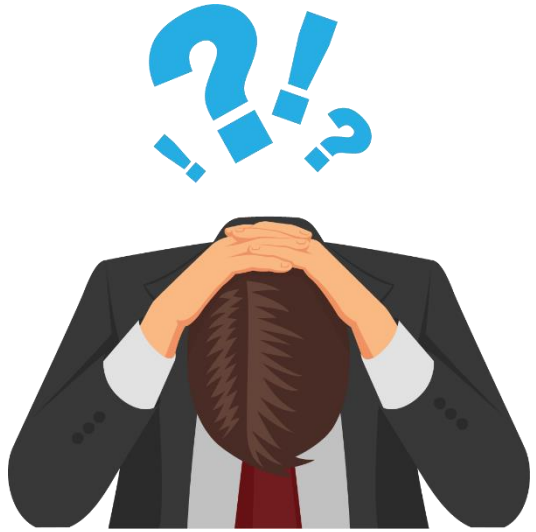






So many systems

- Most life-science oriented IT systems are more or less hardcoded for certain use
- We have systems for: SOPs, QMS, CTMS, eTMF, PLM, NCR/CAPA, BPM, DHF/DMR, Audit, eCTD, LMS, ERP, etc. etc.
- Each system needs its very own:
  - Vendor selection process
  - Contract, budget and licenses
  - Hosting solution
  - Migration project
  - Completely different user interface and thus learning curve
  - May need to be formally validated
- Plus the vanilla "no-systems" i.e. email and spreadsheets



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Result: Too Many Information Silos

multiple, fragmented repositories

difficult to find information

low user adoption

SharePoint
Exchange
OneDrive
box
OnBase by Hyland
Laserfiche
opentext™
documentum
iManage
Dropbox
Google Drive
Network Folders
FileNet
Docuware
syncplicity by EMC
salesforce

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THE ALTERNATIVE

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M-Files is an agile, multi-purpose ECM platform

For both GxP critical and regular business use

- One server in your own server room, or in the Cloud
- One set of user licenses
- Any number of solutions - with unified user experience
- Start from QMS template, and configure it to your needs
- Use the single system for basic document needs…
- …all the way to complex, GxP critical solutions

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Let's clarify a bit

- An M-Files system consists of ***Vaults***
- Each Vault has:
  - Database data (content)
  - Documents (content)
  - Workflows and processes (what you ***do*** with the content)
- M-Files QMS is a ***Vault template***
  - It's one of many
- Use it as is – or use it as a starting point and configure locally to your needs

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But where to start?

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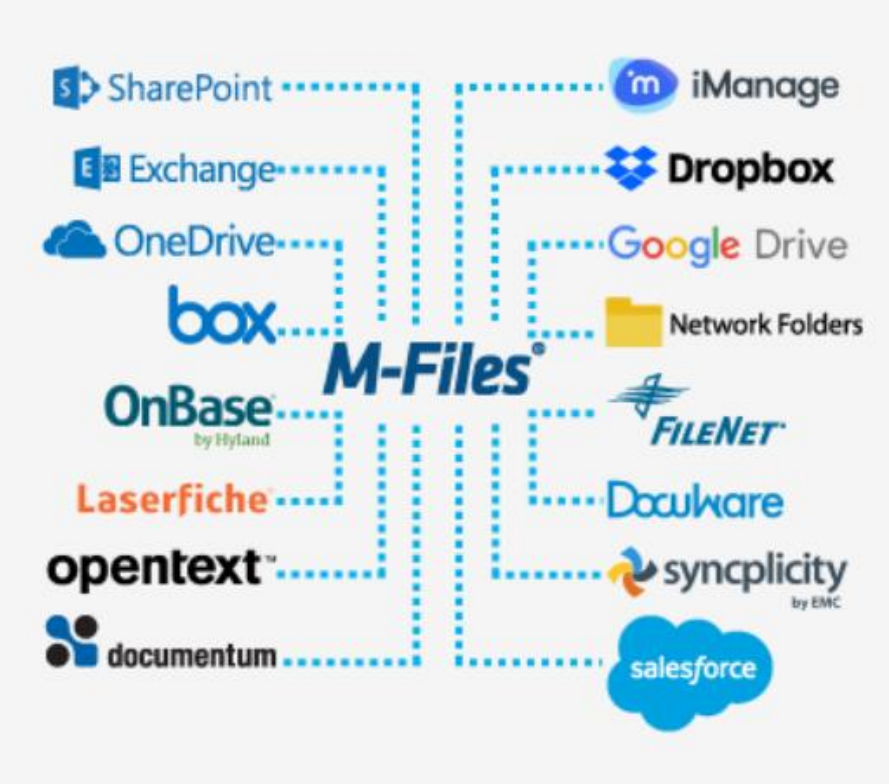
Often it all starts with basic ECM needs

- Find & organize large document volumes
  - That typically are all over the place
- Connect to existing document systems - no migration
- Enterprise search
- Start using mobile apps
- Location-agnostic, folder-free architecture

ROI comes from essentially finding documents



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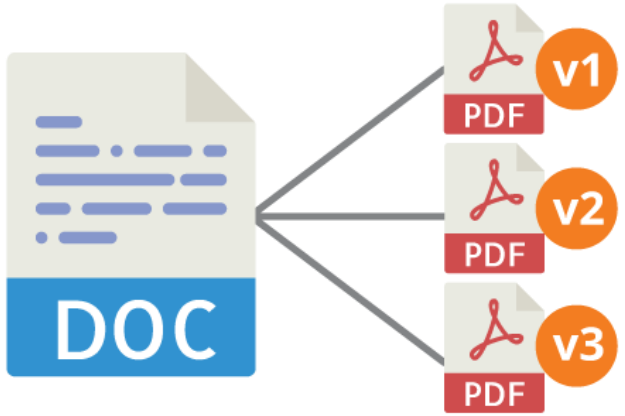
Next steps after basic ECM

- Once documents are found, we ask:
- What can an M-Files QMS system ***DO*** for us?
- And, is it compliant? Can we use it as the sole repository for official company records?
- One idea: use advanced document capabilities
  - Add workflows
  - eSigning
  - PDF overlay processing
  - Document learning etc. etc.
- Or, go full-blown QMS



ROI comes from running the business & staying compliant

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Document control shopping list: option one

To do this:

1. Drafting, collaboration
2. SOP handling
3. Records management, Archiving
4. eSigning
5. PDF Processing
6. Quality process modelling
7. Learning-training-qualification
8. Audit - NCR - CAPA
9. Publishing to trusted 3rd parties

Must implement this:

1. File share & co-authoring
2. Compliant DMS system
3. RM system
4. Digital signature solution
5. Dedicated PDF tools
6. QPM/BPM software
7. Learning Management System
8. Quality process solution
9. Cloud-based publishing portal

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Document control shopping list: option two

To do all this:

1. Drafting, collaboration
2. SOP handling
3. Records management, Archiving
4. eSigning
5. PDF Processing
6. Quality process modelling
7. Learning-training-qualification
8. Audit - NCR - CAPA
9. Publishing to trusted 3rd parties

Just get:

M-Files® QMS

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Essential Compliance Features

- Full audit trail & version history of ***all*** content and ***all*** activities
- Mandatory workflows - graphical editor
- Built-in electronic ***and*** digital signing
- Ensure content is also ***trained***
- Powerful PDF processor built-in
- Best-in-class permissions management
  - Metadata-driven automatic permissions

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Why customers choose M-Files QMS

- Ease of use meets 'GxP' requirements
- Full document life cycle in one system
- Configurability, configurability, configurability
- More than a static collection of quality documents
  - Run all daily quality processes & capture evidence
- System tailored for us – with a modest sized project
- Integrated process maps and flowcharts
- Build several solutions over time
  - Single server or cloud instance
  - One set of licenses
  - Several solutions or areas of use

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Multi-language environments

- M-Files is available in 32 languages
- User can switch the UI language to what they prefer
- Searches are language sensitive
- Local metadata structure can be localized
  - And you can do it yourself – in Excel
- Documents can be in any language
- …including ***multi-language documents***

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