

Document & Content Management For Compliance

Element3 Solutions have partnered with World Class technology providers to give our customers access to technology systems, enabling turn-key business software solutions. Element 3 Solutions will additionally provision, configure and monitor your server to ensure you just use technology, not worry about technology.

M-Files®

M-Files is an easy and practical solution that helps organisations and related businesses fulfill the documentation requirements associated with quality regulations, compliance and standards. Standards and regulations such as ISO 9001, FDA 21 CFR Part 11, EU GMP Annex 11, HIPAA and SarbanesOxley, set certain requirements for document management that can be easily met with M-Files.

Applications in Pharmaceutical, medical device manufacturing, biotechnology, financial, public records, and other highly-regulated industries have in-depth compliance requirements – meaning you need to stay on top of content management needs related to industry compliance, electronic records, auditing, signatures, electronic submissions and transmissions and more.

ARE YOU EXPERIENCING ANY OF THE FOLLOWING?

- Need to demonstrate compliance for TGA, ISO FDA SOX GMP and more.
- Manual and paper based record keeping
- Storage issues for documentation that is required for compliance
- Difficulty finding the right documents at the right time
- Staff knowing compliance related processes and requirements
- Challenging compliance audits

6 WAYS ELEMENT3 SOLUTIONS CAN HELP YOUR COMPLIANCE NEEDS

Secure, Automated Access Control

Unlike traditional ECM systems, which are more restrictive and make use of antiquated security models based on folders, permissions control the M-Files way means that a document's final access control settings are derived from its metadata – and it is done so in a highly dynamic way, with changes to the metadata driving changes in document permissions – instantly and automatically. This one-of-a-kind architecture provides a revolutionary way for M-Files customers to manage access to confidential content.

eSigning

With the M-Files eSigning & Compliance extension, you can maintain compliance with regulations such as FDA 21 CFR Part 11 and EU GMP Annex 11 more easily than ever.

Electronic Approval & Process Workflows

Build efficiencies by using M-Files Workflows for approval or other business processes to electronically route and keep track of documents through every step of the process.

Assignments

M-Files assignments allow easy and relevant assignment of work tasks, including a time-bound and managed deadline. Instantly you have removed the difficult to track and manage, disconnected distribution of communication and requests via traditional methods such as emails and meetings.

Document Version Control & Publishing

Ensure staff are working from the correct version of documentation, not old deprecated versions. The publishing function of M-Files allows document authors to work on new versions that are not ready for release, with no risk of the document being used before approval.

Audit Trail for Audits

Make compliance audits a breeze by simply giving your auditors access to the M-Files system. They will be able to quickly access all compliance check information digitally, saving you countless hours in traditional audit preparation.

Element3
SOLUTIONS