



M-FILES eSIGNING & COMPLIANCE

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

If you need reliable eSignatures and process control capabilities, as well as data processing system compliance with standards and regulations such as FDA 21 CFR Part 11 and EU GMP Annex 11, the **M-Files eSigning & Compliance** Module is for you.

WE SPECIALIZE IN HELPING REGULATED BUSINESSES STAY COMPLIANT



MODULE OVERVIEW

- Electronic signing for documents, audit findings, CAPAs and more...
- Out of the box compliance for requirements like ISO 9001, FDA 21 CFR Part 11, etc.
- Powerful authorization control
- Faster approvals with automatic display of content waiting for signature on users' task lists
- Simple workflow approval
- Audit trail with time-stamped records
- Efficient handling of multiple signatures with batch approvals

LOG EVERY EVENT

M-Files standard event logging tracks most document operations, like file downloads and edits. The **M-Files eSigning and Compliance** Module extends the standard M-Files event log to include all object-specific operations, including:

- Object Access Control List (ACL) modifications
- Object un-deletion
- Version labeling is logged with the assigned label. For each labeled object, only one event record is generated even if label is removed from other versions.
- Workflow state transitions are easy to track
- Document file content change events

Logging these events is mandatory to comply with certain regulatory requirements, including FDA 21 CFR Part 11.

SIGN ELECTRONICALLY

The **M-Files eSigning and Compliance** Module allows your administrator to configure workflow state transitions with a pre-/post condition that requires an explicit electronic user signature. The group of authorized signers can be implicitly indicated by setting the user permissions for the state transition accordingly. This eliminates a need for maintaining a separate list of authorized signers.

Notice that M-Files eSigning and Compliance Module does not support digital signatures. These solutions are available separately

AUDIT TRAIL: OBTAIN DETAILED INFORMATION OF EVENT RECORDS

The **M-Files eSigning & Compliance** Module will provide your administrator with detail on every selected record in the event log, including the affected object, object type, event time, involved users, edited values and much more. The administrator is also able to print reports from all the events or from the individual event details.

An administrator can export the audit trail to an external XML file. This feature allows the user to specify the event type and range to be exported. Additionally, the export file can be split into smaller units.

WANT TO LEARN MORE?

M-Files eSigning & Compliance Module is a useful addition to your M-Files Enterprise Content Management System. For more information on improving your document handling with eSigning & Compliance contact M-Files today at sales@m-files.com

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