M-Files® for Pharmaceutical and Life Sciences

Easy to Use Solution for Compliance with Industry Regulations and Standards

M-Files for Pharmaceutical and Life Sciences is a family of easy-to-understand, out-of-the-box content management solutions for highly regulated pharmaceutical and life science businesses. The regulations set by the US Food and Drug Administration (FDA) regarding electronic records, electronic signatures and electronic submissions (Title 21 CFR Part 11), as well as similar rules set by the European Commission (EU GMP Annex 11), apply to information technology and related systems used in connection with regulated activities, including process control, documentation and data processing systems.

Both FDA 21 CFR Part 11 and EU GMP Annex 11 regulations require organizations to have procedural, administrative and technical controls in place. M-Files offers technical controls out-of-the-box, and helps with administrative and procedural controls by offering a comprehensive toolbox of checklists, training material and document templates as components of the solution. As a result, organizations using M-Files typically attain compliance with industry regulations more quickly and efficiently, and experience greater success in associated regulatory audits.

M-Files for Pharmaceutical and Life Sciences addresses five key areas from Standard Operating Procedure management to Submission management.

M-Files® for Pharmaceutical and Life Sciences				
SOP management	Clinical Trial Management System (CTMS)	Training Management	Electronic Trial Master File (ETMF)	Submission management

Use your favorite CRM or ERP as a master data source!

M-Files for Pharmaceutical and Life Sciences also supports popular CRM and ERP systems such as Microsoft Dynamics CRM, Salesforce CRM, NetSuite, and Microsoft Dynamics GP, AX and NAV. The M-Files interface allows CRM and ERP records, such as accounts, contacts, products, etc., to be utilized as master data in M-Files, enabling related documents and information stored in M-Files to be tagged to the corresponding records in the CRM or ERP. For instance, a proposal in M-Files can be tagged to a particular account in the CRM, or a work order or bill of materials can be tagged to the corresponding record in the ERP. Users can then find any related document directly from the interface of the CRM or ERP system.

When used in conjunction with the organization's CRM and/or ERP system, M-Files becomes a central repository for all important company documents and information that workers can access from other important business systems in a unified and consistent way.

The result is an increase in efficiency, productivity and quality by providing instant and consistent access to critical documentation from anywhere, while also ensuring that strict compliance requirements are met.

M-Files® Features & Benefits Overview

- Professional, full-featured content management system available in cloud, on-premise and hybrid configurations
- Support for regulatory compliance and quality management systems standards, including those associated with electronic signatures, meeting FDA 21 CFR Part 11 and EU GMP Annex 11 requirements
- Manage and track electronic records through their lifecycle, from creation to disposal, including:
    - Seamless integration with Microsoft Office products (Excel, Outlook, PowerPoint and Word)
    - Support for all Windows applications using standard File Save and Open commands
    - Compatible with any scanner, including support for TWAIN and WIA interfaces
    - Integrated Optical Character Recognition (OCR) for generating "full-text" searchable PDF files
- Instantly locate documents by searching on metadata properties or "full-text" content
- Easily classify and organize documents by any property or tag, such as project, document type, date, etc.
- Flexible workflow capabilities enable automation of essentially any process, from simple review and approval to sophisticated, multi-step workflows with multiple stakeholders, assignments and notifications
- Seamless integration with external systems including CRM, ERP, accounting systems and so on.
- Automatic version history maintains a record of every change
- Check-in / check-out facilitates team collaboration and avoids conflicts and eliminates data loss that can occur when one person overwrites the changes of another
- Secure access permissions by document with Windows Active Directory support ensure that only authorized personnel access confidential or sensitive information
- Audit trail and event log record all document activity
- Mobile device and Web Access allows secure anytime, anywhere access to important documents and information
- Reporting and analysis for improved Business Intelligence and management decision support
- Offline use lets you to access your records even without Internet connection

M-Files is easy to deploy, learn and use, and has enabled thousands of businesses in over 90 countries make dramatic gains in efficiency and productivity by improving the way they organize and manage their business documents, information and processes. M-Files is available in 24 languages and is used by customers in regulated industries, such as Addex Pharmaceuticals, AstraZeneca, MedTrials, Bentley Instruments and Parker Hannifin. For more information, visit www.m-files.com.

Additional information

For additional information or a demonstration, please contact M-Files Sales at sales@m-files.com, or visit our Web site at M-Files for Pharmaceutical and Life Sciences.