

## **M-Files QMS Deployed by MolecularMD for Laboratory Documentation and Process Management**

*Provider of Diagnostics Products and Services to  
Pharmaceutical and Biotech Companies Implements M-Files QMS*

**DALLAS, TX, May 14, 2013:** M-Files Inc., the developer of [M-Files](#) metadata-powered cloud, on-premise, and hybrid enterprise content management (ECM) solutions, today announced that [MolecularMD](#), a provider of molecular diagnostics products and services to support the development of targeted cancer therapies, is deploying M-Files QMS to more effectively manage laboratory documentation and information-based processes.

As a regulated laboratory, MolecularMD is required to maintain standard operating procedures (SOPs) and related policies pertaining to nearly every aspect of its operations. The metadata-based M-Files QMS solution enables MolecularMD to establish a single, secure repository to more effectively manage SOPs and corrective and preventative action (CAPA) documentation and associated processes securely behind its firewall to ensure only the most current and up-to-date information is available. In addition, the company has established permission controls and leveraged the workflow capabilities in M-Files QMS to ensure only authorized individuals can access, edit and approve certain documents, objects and processes.

"One of many areas that M-Files QMS has streamlined our document workflow process is with SOP creation," stated David Bennett, IT Applications Analyst at MolecularMD. "M-Files QMS provides us with a controlled framework for SOP creation, handling the entire document lifecycle from the initial document request, document creation, document approvals, distribution, automation of document training requirements, and eventual retirement."

"M-Files QMS enables us to control and regulate document access, control revisions across multiple departments, and utilize electronic signatures for approved procedures," stated Kevin Hawkins, Director, Quality and Regulatory Affairs at MolecularMD. "We can also provide the necessary level of automated notifications and communication to those who are affected by the changes. M-Files QMS is ideally suited to meet the complexities of our business."

"M-Files QMS provides MolecularMD with an efficient and effective metadata-powered SOP management system that will empower the company to automate change control processes, which in turn will increase efficiency, ensure compliance and improve overall profitability. By automating change control tasks, MolecularMD will eliminate common errors experienced by companies that still use manual and/or paper-based systems for SOP management," said Greg Milliken, president of M-Files Inc. "With M-Files QMS, MolecularMD is transitioning to a fully electronic system for establishing document and data control workflows within their existing quality management framework and will be able to more effectively manage critical and sensitive information and processes that affect quality and compliance."

### **About MolecularMD**

MolecularMD provides innovative and reliable molecular diagnostics products and services to support clinical development, regulatory approval, and commercialization of targeted cancer therapies. Using both gold-standard and cutting-edge platforms, they design sensitive, specific, standardized assays that

provide robust, reproducible results in an expeditious manner appropriate for decision-making by clinical investigators, sponsors, community physicians and patients. For more information, visit [www.molecularmd.com](http://www.molecularmd.com).

#### **About M-Files QMS**

M-Files QMS is a practical and easy-to-use solution that helps manufacturing organizations and related businesses fulfill the documentation and data requirements associated with quality standards such as ISO 9001, CE marking or labeling, compliance with FDA 21 CFR Part 11 and EU GMP Annex 11, and audits associated with all of these activities. M-Files QMS is ideally suited for businesses in regulated industries such as pharmaceutical and life sciences, petrochemicals and other process-related manufacturing sectors, food production, transportation (including aviation, automotive, etc.), mining, and others. For more information, visit [www.m-files.com/qms](http://www.m-files.com/qms).

#### **About M-Files Inc.**

M-Files enterprise content management (ECM) solutions transform how businesses manage, secure and share information with a unique metadata-powered approach that organizes and processes content based on *what* it is, rather than *where* it resides. Thousands of businesses in over 100 countries use M-Files on-premise, in the cloud or in hybrid environments to improve productivity and quality, and to ensure compliance with industry regulations and standards, including companies such as AstraZeneca, SAS and EADS. For more information, visit [www.m-files.com](http://www.m-files.com).

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