



"It was difficult to find the right balance of easy everyday use and the full capabilities for our compliance requirements. M-Files was the only candidate in our comparison that had that combination."

-Mika Salonoja
CIO,
Encorium

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Success Story

Encorium employs M-Files document management to support drug trials from start to finish

In industries where all players have to comply with the same rules, a "regulation by rumor" tends to develop, says Mika Salonoja, CIO of Encorium. Certain management practices are not dictated by law, but still become commonplace because it's rumored that other players in the market are using them.

This thinking often seeps into many IT infrastructure and software decisions in the pharmaceutical/life science industry.

"People tend to choose the systems that everybody already uses. In my opinion, the value of name recognition is too high for software -- way too high."

Choosing a document management system based on requirements

With locations in more than 15 countries across Europe, Asia, and Latin America, Encorium is a contract research organization (CRO) that specializes in administering trials for new drugs and vaccines.

When it came to selecting a digital document and records management solution that could help expedite trials while also tracking documentation according to FDA rules and Good Clinical Practices (GCP), Encorium relied on a more rational process than rumor. Salonoja compiled a 64-page user requirements specification document, functional needs, and other specifications. This gave Encorium a comprehensive overview of their needs and requirements.

"We ran a comparison of 11 different offerings," he says, "including two of the so-called 'industry gold standards' for document management."

At the end of the evaluation, however, a dark horse surpassed all of them. "From a technical and operational point of view, M-Files was the clear winner," Salonoja says.

Salonoja was familiar with one major M-Files deployment in the same industry, at the European pharmaceutical giant AstraZeneca. "AstraZeneca used M-Files in its marketing division and not for what we were planning to do, that is, to actually run the clinical trials with that system."

He was soon reassured once he learned M-Files is used to handle complex document compliance requirements in many other industries.

"In Finland, M-Files is used in the aviation industry as a Standard Operating Procedure (SOP) system for servicing certain civil airplane engines. Now I'd say those guys have some rigid SOPs to follow, and strict requirements about SOP learning that



"We have had 90 audits since 2000. Either a client or a regulatory body orders an audit once every one or two months. With M-Files, we can locate those documents instantly when auditors ask for it."

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they have to comply with. Clearly, M-Files is being used successfully in many other fields that must adhere to regulatory requirements," he says.

"From an IT point of view, many compliance-based procedures function no matter what the industry: no records must go unaltered; you must leave a trace of every change you make; everybody who logs on needs to be the person he or she claims to be; and you have to be able to recover from all technical disasters imaginable. M-Files has all of those important aspects."

Documenting the clinical trial

Salonoja says a master file for a single trial can easily consist of 50,000 to 100,000 individual documents. In the paper era, one master file for each trial would fill a row of filing cabinets. Final approval of a drug compound typically involves many different types of trials. Delivery of all the documents to the FDA used to require -- quite literally -- a truckload of paper.

Because administrators of a drug trial are bound by regulations to retain all related correspondence, most of the Encorium trial documents are actually emails to and from doctors, drug supply companies, and participants.

"We can have as many as 20,000, 30,000 emails through the course of a clinical trial. One of the things we liked about M-Files was that it provided a very convenient way of saving trial-related emails directly from Microsoft Outlook," he says. M-Files can automatically include emails and attachments into the system, indexing each item with metadata categories. "We did not see this feature in any of the other programs we tested."

Document management for the entire process

For Encorium, the challenge was to place its mass of documentation into an indexed and easily retrievable digital form, but do so in a way that tracks the progress of working documents and revisions as the trials are happening -- not just the finalized versions for submittal.

As it turned out, the document management 'gold standards' that the company evaluated did not deliver the capabilities they needed. These systems did not deal with any of document process before the point of signature.

"Many well-known document management systems seem to be designed for document specialists in records departments -- not for the personnel conducting the trials."

Salonoja believes that document creation, editing, and email exchanges are the areas where error and miscommunication most often creep into the process. Management of documents from the point of creation onward prevents slowdowns, inaccuracies, and lost information during the trials.

M-Files features such as full version preservation, automatic backup, and status-based email notifications gave Encorium the ability to maintain the proper process of the trials themselves, rather than to simply archive finalized records.

"The people creating the files are the ones who actually need a document management system," says Salonoja. "We were not looking for a library catalog system, but rather a set of software tools that actually succeeds in getting documents written, reviewed, and signed in a timely fashion."



And while the 'gold standards' were meant to supplement the large custom workflow systems that already exist in many large corporations, M-Files was a comprehensive solution on its own, which makes it an affordable choice for companies without an extensive customized infrastructure.

"We have configured the system to meet our requirements, but we did not need to customize it at all. We are using M-Files right out of the box, along with M-Files' FDA 21 CFR Part 11 module and workflow templates that we developed together with M-Files consultants. Otherwise, there is nothing particularly different about our implementation. I think this is a testimony on how adaptable the M-Files solution is."

Taming the paper tiger

"Finding documents with M-Files is quick and easy, even from a remote computer. We are now saying to clients, 'please don't fly to headquarters or our office in India or Munich. We can do a remote audit. Provide us with credentials and you can see all the documentation. This will save you money and time.'"

Despite new digital capabilities, some auditors are still insistent on getting on a plane to perform in-person inspections. Salonoja says the industry has been conservative in its rate of accepting technological innovation into compliance policies. The issue of electronic signatures, as another example, remains a controversial subject. Most drug approval submissions still require ballpoint-pen signatures to certain key documents, necessitating the inefficient printing and re-digitizing of documents back into the system after signing.

"Once we can truly do paperless clinical trials, I believe it will speed new products to market. And that is in everybody's interest."

About Encorium

Encorium is a full service Contract Research Organization (CRO). The organization's extensive experience in running a range of studies in all phases, including vaccine trials and early phase (Phase I & II) development, gives it unique advantages in efficient recruitment, comprehensive management and expert trial design. With over 20 years experience in biopharmaceuticals, Encorium employs approximately 200 staff with operational capabilities in 30+ countries, based on operations under own management with experts that are native speakers and through carefully selected Partner CRO's. For more information, please visit. www.encorium.com. ■

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