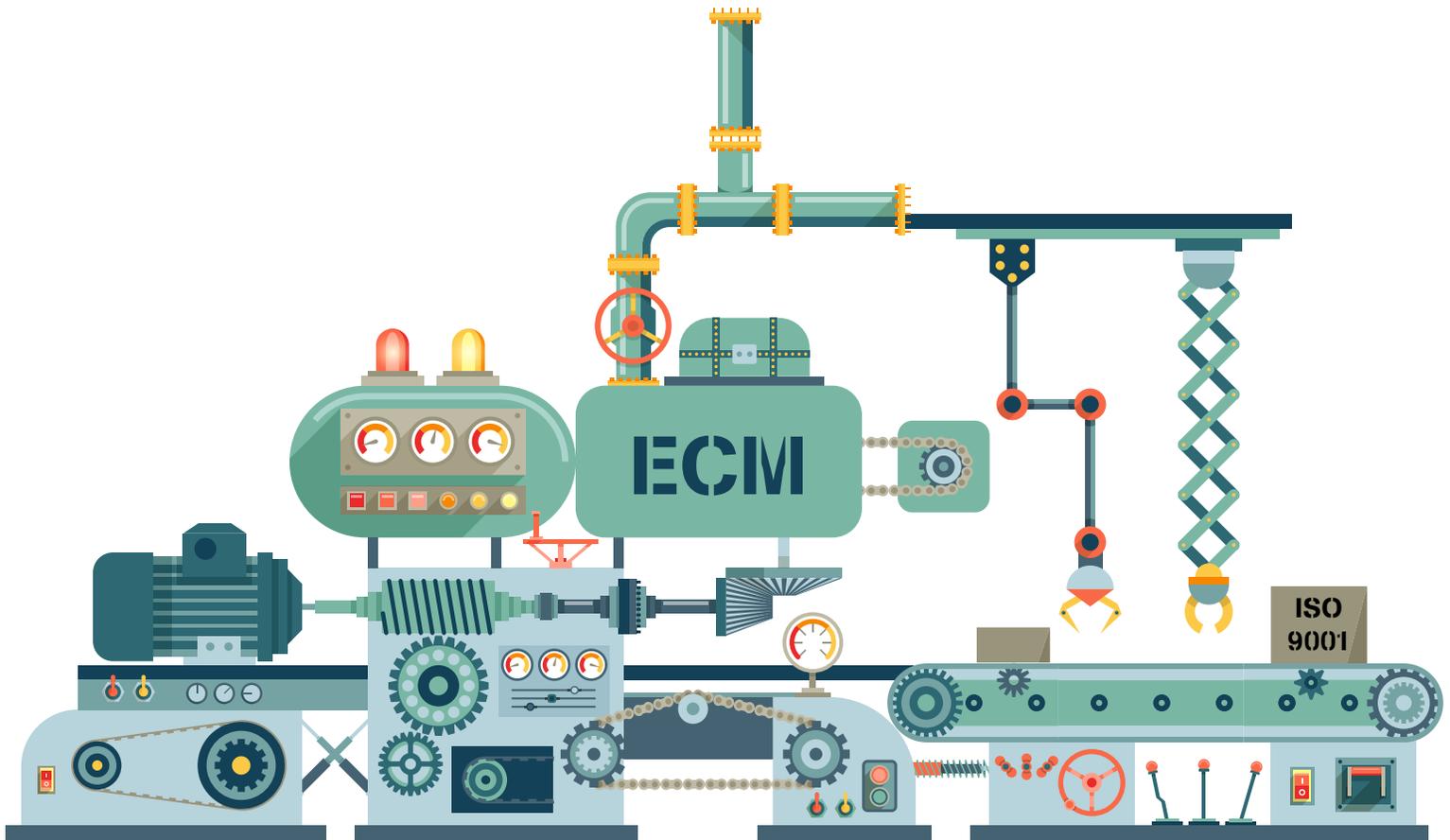


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# 4 Ways Purpose-Built ECM Helps You **Achieve ISO 9001:2015 Certification**



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# ISO 9001:2015 The Clock Is Ticking

Since the ISO 9001:2015 standard was released in September 2015, the countdown has begun for many organizations. Companies have until September 2018 to transition to the updated standard, and leveraging a purpose-built enterprise content management (ECM) solution can be an invaluable tool in this endeavor, while also helping organizations become more efficient and effective in how they manage their content and related business processes.

“If you do ISO 9001 manually, the additional paperwork is a pain, but using M-Files, it’s trivial.”  
-Howard Loewen,  
President MicroPilot”

This paper explains how ECM systems can help automate and simplify many of the information and process management requirements necessary for ISO certification. It makes sense: ISO 2001: 2015 places a much greater emphasis on how information is managed, secured and shared - and ECM solutions provide a way to effectively manage, secure and share content. With this latest edition of the ISO 9001 standard, quality management and business management become more closely linked.

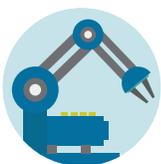


## 1. Embed risk management practices as an integral part of your processes

The latest version of ISO places a heavy emphasis on risk management, and requires that organizations consider potential hazards in their operating environment as well as their quality management system —and then take proactive steps to minimize identified risks.

At a high-level, ISO 9001:2015 places an emphasis on the integration of risk management with business processes. Many organization have performed this by tightly integrating risk management with their ECM solution. It’s difficult to convince auditors, customers, business partners and others that you have taken proactive steps to mitigate risk within your organization if the “process” for managing risks consists of simply listing potential risks in a spreadsheet.

However, when risk management processes are integrated into an ECM system to ensure that, for example, only authorized individuals can access or edits certain documents or that explicit workflows are followed for the review and approval of controlled files, external entities can easily see and verify that risk management is of the highest priority.



## 2. Automate the management of SOPs, learning requirements and CAPAs

Standard Operating Procedures (SOPs) make things easier for everyone —knowing what to do and how to do it is critical for ensuring quality and mitigating risk. Two of the most important aspects of SOP management are templates and workflows.

Since SOPs are often used in many different departments and scenarios, developing SOP templates for the most common use cases ensures greater efficiency and accuracy. Instead of starting from scratch for each new SOP, managers can select a pre-configured SOP template where much of the content is already pre-filled.

In addition, automatic workflows can also be included in SOP templates that can require, for example, each department manager to approve the SOP before it’s issued. By leveraging the workflow functionality of an ECM system, organizations can automate and track formerly manual SOP management processes.

Tasks for training and learning requirements can be automatically assigned and sent to specific groups of employees, who then sign-off on completed requirements using an electronic signature to provide verification of the completed task. Leading ECM systems offer mobile apps that provide the ability for remote staff to access SOPs, participate in workflows and digitally sign documents from their smart devices.

Another area that can benefit from automating via an ECM system is the process for managing corrective and preventative actions (CAPAs). Auditors look for the gap between what a company does and what the procedures say they do. Unavoidably deviations occur, ranging from minimal to calamitous—and when a deviation occurs—the related CAPA must be defined, documented and communicated. The CAPA must then be tracked to verify that the impacted individuals have read and understood the new SOPs associated with the CAPA. The right ECM solution will provide updated tasks as needed for improved corrective management and ensure all affected staff members have read and understood the updated SOP. It takes the guesswork out of the process.



### 3. Provide real time information of KPIs and reporting

The more you know, the better off you are. And with many businesses, this can be extended to: the more you know in real time, the better. ECM systems can provide this valuable real time information for key performance indicators (KPIs). When reporting data related to ISO 9001:2015 activities, how much more useful is it to know you are making decisions with the most up to date information? Today's business climate changes fast. If you are using yesterday's data, you aren't making the best decision for tomorrow. And beyond that, you probably aren't meeting the requirements of the ISO standard either.



### 4. Deliver ROI that extends beyond quality management

The same ECM solutions that help companies become certified with ISO 9001 also benefit other information-driven processes throughout an organization. Quality management is not the only area that can benefit from a solution that eliminates content chaos, ensures control over sensitive information assets, automates and streamlines processes that were previously conducted manually, and integrates with other existing business systems to deliver content in context.

Many organizations have seen a dramatic bottom line impact from the implementation of an ECM system for not only front office operations, but also for back office functions such as human resources, accounting and legal by reclaiming the amount of time spent looking for the precise versions of documents and manually conducting tasks that can be automated.

## About M-Files®

M-Files enterprise information management (EIM) solutions eliminate information silos and provide quick and easy access to the right content from any core business system and device. M-Files achieves higher levels of user adoption resulting in faster ROI with a uniquely intuitive approach to EIM that is based on managing information by “what” it is versus “where” it's stored. With flexible on-premises, cloud and hybrid deployment options, M-Files places the power of EIM in the hands of the business user and reduces demands on IT by enabling those closest to the business need to access and control content based on their requirements. Thousands of organizations in over 100 countries use the M-Files EIM system as a single platform for managing front office and back office business operations, which improves productivity and quality while ensuring compliance with industry regulations and standards, including companies such as SAS, Elekta and NBC Universal. For more information, visit [www.m-files.com](http://www.m-files.com) or call 1-972-516-4210.