

Why your life science business needs electronic document management

6 reasons to embrace an eQMS
for your document stack

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AIIM, the Association for Intelligent Information Management, estimates that your employees lose an average of 30 minutes every single day just searching for the documents they need to do their jobs.

This is dwarfed by the time lost in recreating or duplicating information that already exists — and the hidden costs resulting from outdated or incorrect information, particularly in a highly regulated industry like life sciences, can only be imagined.

So it isn't surprising that more and more life science businesses are turning to electronic document control software systems to save time, boost efficiency and shore up compliance.

Use this whitepaper to learn the 6 key reasons why it's time for your company to invest in a document management system.



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1. Paper isn't scalable

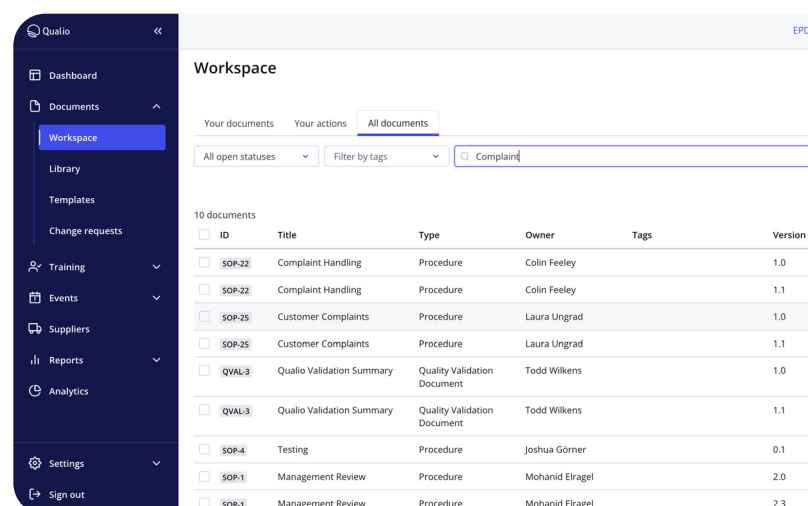
AIIM estimates that even small organizations with a heavily paper-oriented operation spend a minimum of \$25,000 every year on paper production and usage costs. This rises to an eye-watering \$175,000 for larger operations.

On top of that, manual and paper-based systems bring a slew of hidden costs such as:

- Time spent on unavoidable, non-value-adding paper tasks like filing and retrieval
- Duplication of effort as paper records are transcribed into reporting systems or employees unwittingly copy work already completed by others
- Reduced business agility, as administrative tasks like locating and recreating lost documents waste employee time and energy
- General loss of productivity and efficiency

For scaling life science businesses, this approach is unsustainable. As your paper-based QMS expands with your business growth, clutter, confusion and cost magnify too, adding a layer of complexity and waste which compounds every single year.

In contrast, digitizing your document stack and housing it within an eQMS like Qualio eliminates the physical demands of a paper system while slicing the frustrating time spent searching for and managing information.



2. Email: the double-edged sword

The universal use of email to disseminate information, both internally and externally, has revolutionized the speed of communication and slashed information flow and response times.

But it brings considerable challenges while damaging your organizational compliance and audit readiness.

Long email chains, studded with back-and-forth document attachments and uncontrolled document versions, are an almost universal occurrence at businesses with manual document processes. These practices make it difficult or impossible to place your finger on the key touchpoints of an end-to-end document lifecycle.

"When was this document version superseded?"

"In which version were these proposed updates actioned?"

"What role did this quality engineer play in refining Version 3.1?"

Any auditor can be expected to ask these types of questions as they interrogate your document management approach. Answering them by attempting to unearth emails from last year isn't a good look, and could leave you with a series of non-conformances in your audit findings.

Email isn't unique in its unsuitability for compliantly managing information. In the same way, running to the filing cabinet to rifle through reams of paper, or pulling documents from an uncontrolled Dropbox folder, is guaranteed to complicate and weaken your quality and compliance integrity.

3. Control and accuracy

As a general rule, your colleagues won't question established workplace procedures and don't have time to verify or sanitize the information provided to them. They simply *use* documents and information and pass them on. So out-of-date information is retained, and key knowledge is lost when employees leave or change roles.

Where core data is contained in paper records, it has to be manually re-entered into your firm's analysis and reporting systems. This is a costly, time-consuming process riddled with human error that ends with complex, delayed and inaccurate management information.

Replacing this approach with an electronic document system eliminates this problem.

An electronic repository such as Qualio's Documents area holds a single live master copy of each piece of

documented information, readily available to those who need to use it and hidden from others where appropriate. New and updated versions are pushed into the system instantly for everyone, and any reputable eQMS will enforce user permission rules for complete control of how information is shared, updated and distributed across your business.

Plus, a complete audit trail and archive of superseded documents is maintained automatically, removing administrative overhead and automating compliance with key document management benchmarks like GDocP and ALCOA+. Your eQMS will automatically notify designated individuals whenever key documents change, insisting that they retrain and acknowledge where necessary. Endless strings of varying local copies are eliminated as employees can be confident that they can always find the correct information where and when they need it.

4. Cultural change

Closely connected to this newfound accuracy and control of information is the shift to a culture of quality and compliance without employees even realizing it.

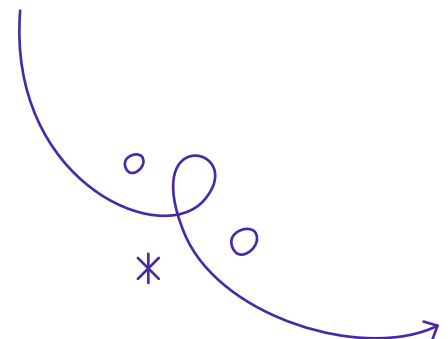
Any eQMS system you use must be intuitive and require minimal user training. With strong internal messaging, this will allow you to drive internal operational changes that are as much cultural as procedural:

- If the document is not in the document management system, then the work wasn't done
- Always use documents or forms directly from the system, not copies that you downloaded months earlier
- Bookmark your Qualio Dashboard and take 10 seconds to check it every day for any outstanding document training you need to complete

To support this cultural change, you should ensure any document management system you choose is flexible enough to be compatible with existing work processes, and do not force employees to radically change the way they work.

For example, your eQMS should not force changes to the office applications, document formatting or other collaboration tools that people are used to, and should not impose an overhead in loading documents into the system.

Which leads us to...



5. Integration

Paper, emails and Dropbox documents just *sit there*, disconnected from your broader business processes and squirreled away in drawers and behind private account logins. At the same time, siloes naturally begin to form between your quality teams and other key departments like engineering and product development.

Your life science company has probably already spent tens of thousands of dollars on management tools for other core processes.

So any truly transformational document management system should smoothly integrate with as many of these existing systems as possible to allow instant business-wide access to key information without the need for extra searching or duplicated storage.

Functionality like Single Sign-On breaks down the barriers to a single source of truth.

Document attachment functionality allows documents generated in typical tools like Office to be loaded into the eQMS quickly and easily.

While quality management software systems such as Qualio also offer powerful integration functionality with tools like Asana, Jira and Azure DevOps, allowing key documented information like design controls, product requirements, test cases and trace matrices to be pulled into a centralized information repository.

Qualio

Dashboard Documents Training Events Design controls Suppliers Reports Analytics

Tertiary Infusion Smart Pump

Open Issues Dashboard Requirements

Changes awaiting review

Code	Title
DIR-6	Drug Administration Acc
DIR-13	Externals Durability
DIR-19	5v rechargeable battery
DIR-20	EMI Shielding

Changes awaiting approval

Code	Title
DIR-22	Example DI 11/16 Webin
DIVER-5	Design Verification - Smart Pump

Design Verification - Smart Pump (Comprehensive)

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Orphaned Missing links

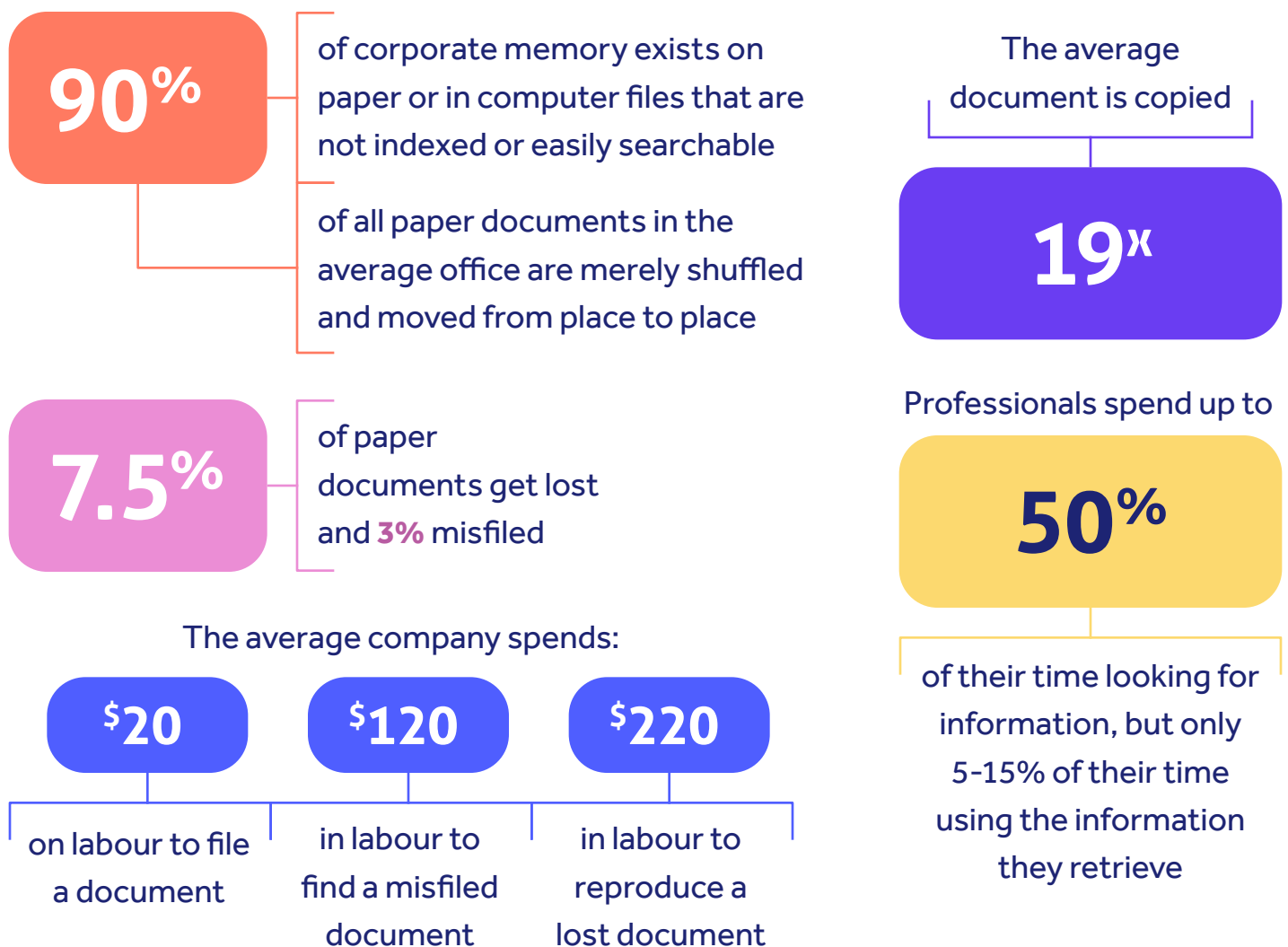
Description

1. Mechanical and physical testing of Product ABC will be completed on both representative devices. The coupons will be used in lieu of final devices for testing that does not require the thickness of titanium).
2. Biocompatibility testing is being conducted on the Product ABC coating as a sterilisation activity. Components used in Product ABC are highly understood biocompatible materials and therefore were deemed unnecessary.
3. At this time clinical data is not required to support the 510(k). A review of current clinical data purposes and can be used to support the 510(k) if requested by the FDA. All relevant data will be attached but will not have specific testing reports supporting the complete review.
4. Sterilisation activities will be conducted through external contract manufacturer. Product ABC is determined to be Gamma Radiation Sterilisation. The full validation of the design control process and documented according to the design control process.
5. All manufacturing activities will be conducted through external contract manufacturer. The validation activities are high level manufacturing activities that will be completed during Phase III of the design process and documented according to the design control process.
6. The validation activities are related to the clinical application of the product. The experienced physicians implanting Product ABC under simulated surgery conditions.
7. Labelling and Packaging Requirements will be documented to be met throughout the design of the device.

Review History

6. More eye-opening facts

By way of conclusion, an information management research project by the accountancy firm Coopers & Lybrand found that:



Investing in an eQMS costs money now. But the ability to generate rapid and transformational return on investment within months should not be ignored.



Ready to take your document management to the next level?

Request a demo today

