DIGITIZE YOUR VITAL RECORDS

WHITE PAPER

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DIGITIZE TO STREAMLINE YOUR PROCESS

INTRODUCTION

Laboratory and product manufacturing records are transitioning to digital-based solutions. While the speed of this transition will vary from company to company, its inevitability is certain. With product development and manufacturing teams experiencing dramatic growth in digital records, the adoption of electronic platforms is accelerating throughout the life sciences industry.

Records can include researchers' drawings, algorithms for processes, graphs and charts, laboratory equipment outputs, and other record types. This data must be stored in a complete format that preserves all the original information gathered. The cost of managing and storing this vital information can be significant. The time research and development teams spend storing, accessing and retrieving records is time not spent on their critical development and manufacturing initiatives.

Because of regulations like Title 21 CFR part 11, pharmaceutical and medical device development and manufacturing teams must keep extensive records of their research and manufacturing processes. With many of these records still paper-based today, the existing paper-intensive, manual processes can impact the transition to an electronic platform. Employees continue to rely on paper to monitor progress and respond to both internal and external requests, like regulatory audit or legal discovery.

Having the right information at the right time is critical to complying with regulators and protecting intellectual property, yet paper documents needed to support responses to regulatory inquiries or litigation are often scattered across locations throughout the organization and external storage. This makes it exceedingly difficult to find information when needed most.

By streamlining workflows with digital information, organizations are able to more fully automate product development and manufacturing processes, speed digital adoption, and deliver demonstrable efficiencies.

Why is this important for records and information management (RIM) managers and life sciences industry business leaders today? When paper is converted to images, information becomes available to approved teams across the globe. Making information available across departments and divisions improves collaboration and decision making, enables product development teams to avoid repeating research, and empowers legal teams to respond quickly to regulatory inquiries and litigation.

INFORMATION IS...
YOUR ADVANTAGE

> The growth of electronic records, coupled with the long retention period required for clinical trial and product manufacturing records, has created an environment in which many organizations must manage physical and electronic records simultaneously.

TODAY'S CHALLENGES

FRAGMENTED STORAGE

Departments across the globe create their own records, which can result in fragmented records generated with different standards. Growth through mergers and acquisitions can also result in a network of documents with inconsistent storage and management policies. It is not uncommon for organizations to acquire physical records without sufficient indexing, and these records are often kept in case they contain vital product development or manufacturing information.

GLOBAL FOOTPRINT

Global expansion adds to the complexity of managing records. Each country may have differing regulatory requirements and their own localized records management functions, without consistency from country to country. When multiple locations conduct research and development or manufacturing, information that is not shared globally may not be accessible to those who need it, and efforts may be duplicated.

HYBRID RECORDS

The growth of electronic records, coupled with the long retention period required for clinical trial and product manufacturing records, has created an environment in which many organizations must manage physical and electronic records simultaneously. In some cases, a manual process, such as a spreadsheet, is used to track physical storage and multiple electronic systems.

INCONSISTENT IMPLEMENTATION

While most organizations have records management policies, individual departments may not be implementing them consistently. Sometimes these inconsistencies are not identified until records are needed urgently by product development, regulatory, or legal teams.

INSUFFICIENT INDEXING

Because of the sheer volume of records generated in product development and manufacturing, consistent indexing is needed to create high-quality metadata. Balancing quick access across the organization while securing proprietary data requires the right technology implemented consistently.

CHANGE ISN'T EASY

Employees will continue to rely on paper because change is difficult. Some employees will resist moving to a more automated approach because they are comfortable with hardcopy lab notebooks and product development records. Others in the organization may be concerned with the security of digital assets.

INEFFICIENT WORKFLOWS

In many cases, paper-intensive laboratory notebooks and product development and manufacturing processes are keeping companies from moving toward global access to vital records. These records are critical in responding to development teams' needs, reducing costs, addressing compliance and discovery requirements, and increasing productivity.

Digitizing your workflow enables you to dramatically improve productivity, reduce costs and enable your organization to respond more quickly and efficiently to discovery and regulatory requests.

TYPICAL APPROACH

If you look at real-world examples, you can see where organizations can achieve significant business value by digitizing vital records in their product development and manufacturing operations.

In one example, Iron Mountain found that a large global generic and specialty pharmaceuticals company was faced with a hybrid of physical and digital records after acquiring another manufacturer. Like all pharmaceutical companies, this company must maintain records for all inactive regulatory documents, such as clinical trial results. Some records were available digitally via an in-house system with a restricted number of terminals, which meant queues formed as staff tried to access electronic documents. The deep archive was only available as paper records that were stored manually at multiple locations. Iron Mountain created a document management solution that met their high standards of security with a seamless digital records center hosted offsite. The in-house investment in scanning was not wasted, and Iron Mountain also scanned the manual deep archive and prepared regulatory and legal teams to be able to respond to audit or litigation events.

DIGITIZE YOUR WORKFLOW

Digitizing your workflow enables you to dramatically improve productivity, reduce costs and enable your organization to respond more quickly and efficiently to discovery and regulatory requests. By digitizing, you can:

▶ **Implement** consistent records storage and indexing across departments globally through an efficient solution that increases productivity.

▶ **Locate** and securely access vital product development and manufacturing documents quickly in a document management system or in a vendor-hosted archive.

▶ **Eliminate** delays and inefficiencies associated with retrieving and working with physical files by making electronic information available to support product development, regulatory, and legal teams.

▶ **Convert** documents from paper to digital to automate and optimize manual processes in areas such as human resources, accounts payable, contracts and patents.

▶ **Index** and correctly classify documents for secure access to enable research and development productivity gains and faster response times to regulatory audit and legal discovery requests.
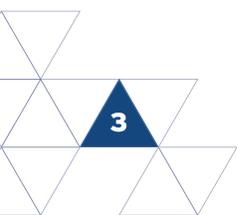
DRIVING BUSINESS VALUE

In addition to cost and productivity improvements, digitizing vital records provides other benefits, and enables organization to:

▶ **Manage growth:** Organizations gain the ability to absorb and strategically manage the dramatic growth of electronic records in a hybrid environment when paper is still part of the process. Digital transformation is inevitable, and organizations must transition or risk being left behind.

▶ **Enhance collaboration:** In reducing duplication of effort by making electronic information available when it is needed, organizations can eliminate many of their manual, paper-based workflow functions. As a result, they are able to create processes supported by technology systems, which can enhance collaboration across groups and divisions globally.

▶ **Set the foundation for next-generation business initiatives:** Streamlining workflows and managing the quality and integrity of data are becoming increasingly important factors in business initiatives centered on cloud services, mobility, social media and big data. Global research and manufacturing teams will leverage these tools to speed product development and refine key processes. Building the right processes and deploying the right tools and technologies now will not only drive immediate business value, but it will continue to provide benefits for many years to come.

Conclusion

As with many of the challenges facing RIM in life sciences organizations, a key obstacle to "going digital" is not knowing where you will make the biggest impact and, in some cases, not knowing what "good" looks like. For many companies, security of digital records is a key concern. Fortunately, there are vendors that have significant experience in knowing how to digitize, remove paper from workflows, and drive business value, now and in the future.