

Establishing Records Management Excellence Across a Life Science Company



Establishing records management at an enterprise level necessitates cross-functional collaboration and stakeholder buy-in. Although process ownership is typically driven from legal, it is ultimately every employee's responsibility to ensure compliance. Records not only provide historical context to business transactions but are also considered inalterable documents safeguarding organizations from potential harm.

Establishing records management as a fundamental component ingrained into the backbone of an organization requires development of robust practices. When these practices are well established, they ensure the level of compliance required from health authorities in approving therapies and medical devices for patients in need. With robust records management practices, companies

The International Organization for Standardization (ISO) 15489-1:2016 defines records management as a “field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records, including processes for capturing and maintaining evidence of and information about business activities and transactions in the form of records.”¹

can anticipate needs; optimize processes; and generate revenue, control costs, and mitigate risks as the organization's records grow. However, when these processes fall short, companies open themselves up to risks such as delays, discovery, legal holds, lawsuits, and hefty fines.

The life science industry is accelerating in its creation of critical records. The breadth of digital mediums and technologies used to convert physical records to electronic records has produced a complex network of document systems ranging from regulated to unregulated repositories.



Often, organizations encounter notable disparities between their internal business functions regarding the level of comprehension for records management compliance and their responsibility to maintain it. Organizations should establish and maintain effective records management frameworks to ensure compliance across all functions.

In this red paper, we will detail the challenges organizations face when implementing and sustaining enterprise records management processes and provide recommendations on how organizations can alleviate the burden on their resources and avoid potential barriers.

Scalable Solutions for Records Management Needs

For both small and large organizations, implementing effective records management practices calls for cohesive organizational alignment and establishment of well-defined processes for retention and disposal of critical records. However, the proficiency of an organization's records management practices does not always correlate to its organizational proficiency.² Given this disparity, it is imperative for even experienced organizations to recognize potential barriers in establishing competent records management frameworks and to prevent downstream ramifications (eg, fines, delays) for inchoate practices. Common, yet avoidable, pitfalls include:

1. Disjointed records management program
2. Organizational apathy toward records management
3. Non-compliant records management infrastructure
4. Limited stakeholder comprehension of records management processes

The design and implementation of a records management program should be founded

on a cross-functional, global, scalable process that drive consistency and compliance.

1. Creating a Cohesive Records Management Program

As organizations grow, so do their respective business functions. Ensuring organizations have effective records management capabilities is essential to maintaining compliance. However, establishing and applying this capability across new or pre-existing business functions can present difficulties. To ensure consistent operation and compliance, organizations need to define their bedrock processes and roles.

According to the Association of Records Managers and Administrators (ARMA) International, one out of three organizations is deficient in records management and roughly one out of three reports only having the essentials to operate.² Risk indicators signaling an organization is experiencing divergent records management practices include:

- Unclear records management advocate network roles
- Undefined records retention schedules and/or records repositories
- Outdated processes that are not applicable to all records media (electronic versus physical)

To alleviate these risks, organizations need to take a cross-functional approach in documenting the ideal future state of their records management process and in addressing gaps, risks, and concerns in the current state. A cohesive records management program ensures both the process and the roles are well defined.

Defining the Process

The records management process begins with the creation or receipt of a record and continues through its maintenance, and eventually, disposal. These activities mark pivotal milestones within a record's lifecycle, each of which is governed differently depending on the nature of the record or the record type. Organizations should consider how well defined these processes are based on the three major milestones: creation/receival, maintenance, disposal.



As organizations develop in their records management processes, it is important to continuously support these initiatives. This will ensure that enhancement of processes are functionally exhaustive and robust enough to encompass all stages of a record's lifecycle. It is important to note that a process is only as good as how well it is executed. Stakeholders must be bound by these guardrails and be vigilant in reinforcing set standards, in addition to management's provision of supportive frameworks for stakeholders to fall back on.

Everyone is a stakeholder when it comes to records management. The synergistic nature between process and role requires organizations to communicate and align on what these both mean for their organization's maturity and growth.

Defining the Roles

To execute and maintain records management processes most effectively, organizations should define and deploy a records management advocate network. This network is composed of individuals who ensure records are maintained via a compliant process and reinforce records management comprehension across the organization. Records management advocate network roles are not static; rather, they are fluid, allowing for scalability against the needs of the organization.

Pivotal roles for records management efficiency often include the roles shown below.



Records Owner

Responsible for creating and/or receiving records



Records Curator

Responsible for managing the lifecycle of records



Records Champion

Responsible for acting as a functional champion for record policies (eg, records retention)



Records Administrator

Responsible for acting as a functional administrator for maintenance of records

Together, these roles effectively bridge processes and people to positively influence records management practices and behaviors. As noted previously, these roles can be multifaceted where personnel can

perform one or many of the defined roles. As the organization grows, the network can evolve to meet the demands and needs of its records. Furthermore, each role's responsibility will be molded and shaped based on the influencing forces (ie, regulations, guidance, compliance, etc.) experienced in a records management environment.

2. Embedding Records Management Into an Organization's Culture

Creating and maintaining a compliant records management culture that is focused on the required capabilities requires the application of change management strategies. Organizations that find themselves in a reactive mode by applying patchwork records management methodologies risk taking an ad hoc approach in an attempt to meet basic compliance requirements. This short-sighted tactic may ultimately prove unsustainable over the long term. To transition to a more proactive state, organizations need to utilize change management strategies such as establishing clear communication plans and support mechanisms, and instilling capability importance within their leadership teams. According to ARMA International, three out of five organizations are performing change management activities as a reactive measure, while only two out of five are applying forward-thinking strategies.² Key symptoms to watch for in an organization when diagnosing change management efforts include:

- Stakeholders are not aware of records management standards
- Functions do not have proper recordkeeping procedures
- Stakeholders are unable to identify records management storage locations
- Governance structures do not include records management personnel

Ways in which organizations can tackle these challenges include uniting change management strategy and execution to deliver high-impact messaging that penetrates down into day-to-day operations. Engaging stakeholders and communicating changes effectively will ensure systematic implementation and lasting adherence to records management practices.



3. Implementing Programs Across Compliant Environments

Records management has drastically changed from its beginnings when physical media was common practice and file rooms housed all critical records. Compliance has always included people and process components. However, with the digital age accelerating, companies are forced to rapidly adopt new and ever-changing technologies to store and manage their records. According to ARMA International, nearly three out of four organizations are proactively improving their infrastructure, indicating increased interest toward maintaining and optimizing these processes.² With that in mind, records management has very much become a people, process, and *technology* effort.

Organizations can assess their current state practices to identify redundancies in record repositories, record processes, and system gaps, as well as define areas of opportunity to disentangle duplicative systems and solutions within the records management environment.

An existing system's landscape of document management systems can be assessed to identify and reduce redundancies and gaps and to minimize duplications. Additionally, underpinning these systems with integrated and flexible platforms (ie, OpenText, Hyland, Alfresco, Box, etc.) is another step organizations can take to sufficiently capture non-validated records management activity (ie, storing files in systems with no records retention schedules or audit trail). By implementing these solutions, organizations will be able to effectively maintain record types per their designated records retention schedules and properly safeguard stakeholders from non-compliance to ensure operational excellence.

4. Reinforcement Is the Best Enforcement

Successful execution of robust change management strategies will not in itself ensure the longevity of stakeholder records management knowledge retention or perception. An additional aspect to establishing successful long-term strategies is to reinforce stakeholder learning journeys by implementing records management advocate networks and providing relevant role-based resources. Both elements address different dimensions of a stakeholder's understanding through comprehension and adoption of records management concepts.

Key signs that stakeholders need reinforcement include:

- Stakeholders have limited understanding of records management requirements
- Stakeholders have limited understanding of their role in records management
- Stakeholders are unable to identify their records management advocate network contacts

Organizations should strategically establish critical records management roles across the organization to ensure all business units are appropriately supported. This level of coverage allows the business to lay supportive advocate networks throughout the enterprise while documenting the granularity of role-based records management activities and capturing necessary functional insights to avoid common pitfalls. Establishing long-term knowledge management assets and continuity learning milestones leads to improved stakeholder adoption and retention.



Conclusion

The framework of an organization's enterprise records management capabilities is multifaceted and cross-functional. The strategies utilized to execute and maintain these capabilities should extend across the business and effectively educate and instill lasting change in all stakeholders and roles. As organizations continue to innovate and supplement processes with new technologies, it is essential to address those critical areas of need and establish the fundamental components of a comprehensive and scalable records management program.

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2. *ARMA International. Information Governance Maturity Index Report — 2020.* March 2020.