



Nine Steps for Launching an

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ERM ECOSYSTEM PLAN

An electronic records management (ERM) solution is not one system, but an ecosystem of policies, standards, processes, people, and tools. Like any ecosystem, it will evolve and grow based on the environmental factors surrounding it. Some of the factors that determine how this ecosystem flourishes are the industry, regulations, corporate culture, organizational commitment, and demonstrated value. This case study from an organization in a highly regulated industry provides a nine-step plan for building such an ecosystem.

Rapid Growth Demands Solution

With the rapid growth of this small biotechnology company into an industry leader through strategic investments, mergers, and acquisitions came stakeholder demands to provide a pragmatic strategy for managing and rationalizing its systems and data. The company's legal and IT departments' strategy to meet this demand entailed investing in technology, people, and processes to address different data types and business transactions and resulted in the ERM solution described below.

The Technology

The company considers its ERM solution a program rather than a stand-alone system. First, it is composed of multiple tools rather than just one. Second, it has steadily evolved through incremental investments that began with one questionnaire, one tool, and two staff members. It is now an interconnected suite of tools comprising a solution with core capabilities that include appraisal; auto-classification; redundant, outdated, and trivial (often referred to as ROT) data analysis; disposition; data migration; document holds application; archival; and unstructured, semi-structured, and structured data curation.

The People

The program now is fully staffed with electronic archivists, IT leads, database administrators, and ERM technicians, and it has a compendium of documentation, training, and operating plans that underpin the ERM solution.

The Process

The program is multi-functional and multi-jurisdictional. It is bound by the industry's best practices and the laws and regulations that govern the industry. Key performance indicators are measured regularly and the program is accountable to executive sponsors. Its value is measured via the tangible return on investment from re-tiring systems, reducing maintenance and licensing costs, and decreasing administrative burden.

Business Case Demonstrates Value

A "build it and they will come" strategy for developing and implementing an ERM program simply would not have worked in a competitive environment where companies are constantly challenged to drive and maintain a low general and administrative expense budget. Justifying the need for this program required showing its measurable value. The strategy for the ERM solution business case, then, was to demonstrate how the solution's capabilities would:

- Protect intellectual property
- Support the legal function as litigation and the rules for electronically stored information continually evolve
- Adhere to privacy regulations
- Manage the terabytes of data accumulated through the company's multi-billion-dollar growth strategy

Technology Determines Success

Companies in the biotechnology or pharmaceutical space must consider the industry's stringent regulations and litigious environment when choosing a technology company partner for building an ERM solution. The most important factor for ERM implementation success is to select a technology that can validate against a U.S. Sarbanes-Oxley Act (SOX)-compliant computer system, ensure compliance with regulatory best practices, and meet legal and privacy obligations.

Validation

To ensure the highest quality and integrity of the processes and data contained within a system, computer

An electronic records management (ERM) solution leads to better information management, drives operational excellence, protects the organization during audits and legal matters, and allows for effective information integration activities. This is why building an ERM ecosystem, with the flexibility for continuous improvement, should be on all organizations' strategic roadmaps.

In the business case, be realistic about the savings that can be achieved.

systems that handle GxP data and records are validated in accordance with the U.S. Federal Drug Administration Code of Federal Regulation 11.10(a) and the EU's equivalent, the European Medicines Agency's EMA Annex 11 Section 4.

Because of the rigor of computer system validation to meet the compliance requirements of the SOX, it is best practice to validate an ERM computer system against a SOX-compliant system. The organization then can be assured that any data stored within the ERM solution is sufficiently protected by the controls in place. These controls likely will be audited, and the system owner or business owner will need to be prepared to speak to and defend these controls competently.

Regulatory Compliance

The pharmaceutical industry is governed by what are known commonly as “GxP” regulations, where the “G” stands for “good,” the “P” stands for “practice,” and the “x” is a place holder for letters representing types of practices. For example, GLP is good laboratory practice, GMP is good manufacturing practice, and GCP is good clinical practice.

Each of these good practices is governed by rules and regulations, and biotech and pharmaceutical companies employ quality assurance and documentation experts to ensure that their companies abide by these good practice guidelines.

A manufacturing company should then, for example, study and integrate the International Society for Pharmaceutical Engineering's guidelines for GMP on data integrity prior to implementing any ERM solution that will house its inactive manufacturing records.

Legal and Privacy Obligations

In a multi-jurisdictional and global environment, organizations must be mindful of the laws and their privacy obligations – such as the EU's General Data Protection Regulation – with which they must comply. They should partner with their in-house legal counsel, specifically with e-discovery counsel and the chief privacy officer, to ensure that legal and privacy guidelines are managed appropriately in an ERM solution implementation. For example, if data being ingested and archived contains personal or sensitive information or is subject to legal hold, the ERM system must have a mechanism to note these obligations and manage them accordingly.

A Nine-Step Guide for Others

As experts and innovators in their respective disciplines, the authors of this article developed a roadmap to success others can use to guide them in their plans to launch an ERM solution.

1 Identify the burning platform for change.

Perhaps an organization's “burning platform” (“what's in it for me”) is the need to retire systems acquired from mergers and acquisitions or the need for a secure repository for inactive electronic records sitting on file shares and not readily accessible for audits or investigations. Information professionals who are seeking to develop an ERM solution must work with the records management liaisons within the business lines and with senior management to understand the organization's priorities and pain points. This is critical to getting buy-in and user adoption of the initiative.

2 Earn quick wins and establish credibility.

After getting the buy-in to proceed, find members of the organization who are willing to pilot the tools and then share their success stories with strategic partners to demonstrate the value of the investments.

3 Don't try to “boil the ocean.”

The ERM system will not be everything to everyone. To manage expectations, do not over promise and then under-deliver. Instead, know what the ERM solution does and does not do. For example, if the ERM solution platform is meant to archive inactive records, don't volunteer it as a potential solution for the organization's need for an electronic document management system that can manage live documents and the workflows associated with them. Engaging in that initiative and forcing the system to be that solution will tax resources and disappoint the organization if this is beyond the scope of the ERM system.

4 Establish investment stage gates and deliver on promises.

It is critical to set clear expectations and meet them if the ERM solution is tied to cost avoidance or savings. In the business case, be realistic about the savings that can be achieved. Then focus on gathering accurate metrics for communicating those savings when targets are met.



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For more details, see

<http://discoverarma.org/mentorship>

and the mentor FAQs at

<http://discoverarma.org/mentorFAQ>.



Build the [ERM] foundation, then make incremental process improvements...

5 **Garner executive support and buy-in.**

Even if this initiative is what the organization needs and it is logical to move forward immediately, remember that the organization must prioritize many other pressing initiatives. For this project to rise to the top of the pile, it must have a sponsor within the business who understands the value of the project when it is still in the conceptual phase and is willing to stand behind the business case for funding. In exchange for the sponsor's support, remember to tell him or her when the tool has demonstrated its value and name the person formally as an executive sponsor to ensure appropriate recognition for having supported the successful initiative.

6 **Engage people at all levels of the enterprise.**

Socialize the project throughout the enterprise, from senior management to entry-level technicians and administrative assistants. From the onset, involve program liaisons (i.e., records coordinators) who serve as champions for change, as well as the steering committee comprising other information professionals who provide support and guidance. Ensure that they are aligned with the strategy throughout the process, as this will be critical for effective change management and user adoption once the system is live.

7 **Translate performance into cost savings and cost avoidance.**

The need for metrics cannot be stressed enough. Without capturing data analyzed and ingested, systems decommissioned, and data dispositioned, it will be impossible to justify the investments the organization has made in the ERM solution.

8 **Build an operating plan that governs the program – from executives to execution.**

There are three components to a successful ERM solution deployment: technology, people, and process. Without a logical business process and the people to engage in the process, the technology will sit idle. Think about the operating model while building the ERM solution and define a baseline business process, roles, and responsibilities. Of course, this will be refined as the tool is observed in action.

9 **Monitor and continually evolve the ecosystem.**

An ERM solution will evolve as the organization and its information programs evolve. Build the foundation, then make incremental process improvements

until reaching a transformational phase. This is when the organization is reaching out for service and saying how the tool must evolve to best meet various business needs.

The Destination!

At the transformational phase, the staff will no longer remember a time when the ERM ecosystem and the supporting processes did not exist. Instead, they will be reaching out to help refine the processes upon which they have come to rely. This is the most exciting and rewarding part of the journey, and following these steps will lead to that destination! **E**



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