A PATH TO EXCELLENCE IN THE GLOBAL REGULATORY SUBMISSIONS PROCESS

Driving Efficiency in Research and Development

EMC PERSPECTIVE

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INTRODUCTION

Streamlining the regulatory submission process is essential to getting products to market faster today. Yet for most Life Sciences companies, this process is time consuming, inefficient and complex—even more so when working in a global environment with multiple internal and external partners. The lack of efficient and authoritative global systems results in inefficient communication between corporate headquarters and local affiliates. While sponsors are ultimately responsible for the safety of the products available in global markets, they face major challenges in gaining visibility into regulatory activities. What are the affiliates submitting? How accurate is it? What is the degree of risk?

On the flip side, affiliates struggle to get access to critical submission documentation in a timely manner and to create an efficient process while using a whole host of local tools—spreadsheets, network drives, email, paper and so on—to manage their work. Further, those affiliates have their own requirements at the local level that may differ significantly from the templates and content provided by the corporate office. In fact, Steve Gens of Gens & Associates found during his research that 40% of affiliate time is spent coordinating and managing regulatory information. Approximately 25% of that time is spent on unproductive activities such as data reentry.

Life sciences companies must be confident in the quality of product registration information maintained in global systems while ensuring that affiliates have what they need: information access, flexibility and adaptability, and bidirectional communications. Achieving these objectives requires solutions that support reliable, seamless and simultaneous collaboration between geographically distributed people, regardless of whether they are frequent or occasional participants in the document-authoring process. And it requires a unified approach that consolidates disparate content management systems and applications functioning in silos that impede this level of teamwork.

As a leader in enterprise content management for the Life Sciences industry, EMC offers a unique perspective on both current trends and real needs. This paper takes a fresh look at what makes the regulatory submissions process so unique and challenging, and envisions how software solutions can better support the process with innovative functionality.

ENVISIONING A BETTER WAY

It's clear that Life Sciences companies need an approach that enables regulatory professionals to streamline, standardize and make transparent how authoring and submissions work gets done. The right approach will make it easy for you to answer fundamental questions such as:

- How can we collaborate faster and more efficiently, both internally and with external partners—while reducing errors?
- How can people easily find and leverage previous work that may be years old—but is still relevant and useful?
- How do we shave time off the document authoring and approval process and streamline workflow?
- How can we better guide and assist those participating in the process on an infrequent basis to reduce errors and increase efficiency?
- How can we gain full transparency into the status of submissions authoring, review and approvals so we always know where we stand?
- As regulatory requirements for different markets change, how can we ensure that submissions are complete, accurate and compliant?
- How can we quickly determine which submissions are impacted by regulatory and other changes?
- How can we better support work in global environments with local affiliates?

From a functional perspective, what's needed to make transformational change? What innovations and new thinking are required?

We've talked with R&D professionals at all levels to understand their challenges. Our findings clearly indicate that Life Sciences companies are ready to embrace the following key concepts.

A SINGLE SOURCE OF TRUTH FOR ALL FUNCTIONAL AREAS

In the past, a centralized corporate office typically devised the submissions strategy, prepared and submitted documents, and managed the process. In today's global environment, and with the prevalence of outsourcing to third parties such as contract research organizations (CROs), this top-down approach is no longer practical. For example, a cover letter created in the EU must be rewritten for Thailand; forms required in the U.S. are irrelevant in the EU.

Submissions can involve the orchestration of thousands of documents across a number of products and typically involve multiple functional areas—R&D, clinical, manufacturing—all storing documents in different systems, repositories and formats, both electronic and paper. Yet in many cases, much of the core information is reused across these areas. For example, a clinical study report typically resides in the clinical domain, but because it is submittable to regulatory agencies, is must also be shared with regulatory. A manufacturing specification is required for the submission, but is also maintained in the quality management system (QMS). Documents are imported and exported from one system to another, a time-consuming manual process. Without a way to link the current, approved content directly from the clinical system to R&D, for example, it's a monumental task to find and collect submission-ready documentation, and to manage an efficient review and approval process.

Complicating matters further is the fact that authors must be able to find and search through work that has already been done by themselves or others at some point in the past, leveraging or repurposing it to avoid rework and oversights. For example, sometimes clinical studies are put on hold, only to restart years later after applying new scientific learning.

What's needed is a robust content repository for managing all documents across multiple functional areas, including earlier documentation and data created several years ago. A unified enterprise-wide repository provides seamless access to documents from various functional areas without cumbersome handoffs or the need to duplicate. With an enterprise solution, those documents can be shared without extraneous manual processes for exporting, importing, indexing and essentially rewriting for a different business use.

Because those documents are always the current version, they become the single source of truth across the extended enterprise. The corporate office, still responsible for content, can distribute it to the regional affiliates while enabling them to create local content based on regional requirements, then communicate it back to headquarters. This can help maintain compliance, reduce the workload and add efficiency to the submission preparation process.

STANDARDIZATION AND BEST PRACTICES

Today's R&D professionals demand a simplified, streamlined user experience that empowers even periodic and infrequent users to work like experts. Standardization of processes and use of best practices: that is the key.

Using standards and pre-configuration in document inventories, terminology and vocabularies driven by reference models promotes ease of use through familiarity and repeatable processes, even for occasional users. This approach also simplifies sharing of data across organizational boundaries and systems, and makes it much easier to migrate and merge when a company is acquired. Examples of these standards include the Drug Information Association (DIA) Electronic Document Management (EDM) reference model and the International Committee on Harmonization Common Technical Document (ICH CTD) formats.

Reusable templates and document inventories can serve as a starting point, helping to automatically structure documents based on regional regulatory requirements where drug approval is being sought. The ability to manage ICH-compliant templates within the system—with functionality to automatically populate content based on the document properties and auto-filling of documents based on the standard reference models—promotes efficiency, simplifies processes and reduces the need for training.

Predefined forms for entering critical data for key topics such as compounds and trial information can dramatically reduce repetitive, error-prone manual effort and improve accuracy.

These innovative features enable even inexperienced users to effectively author and manage submission-ready documents, and help ensure that submissions packages include all required content elements. And for affiliates, where time and resources are limited and oversight minimal, intuitive processes reduce the need for training and streamline work activities.

WORKFLOW-DRIVEN COLLABORATION FOR AUTHORING, REVIEWS AND APPROVALS

Collaboration is top of mind for Life Sciences companies today. Within R&D, cost pressures are driving them to collaborate more efficiently internally, and to work more extensively with third parties to execute key business processes.

But collaboration is only a buzzword when people involved in submissions authoring and management are working across organizational and geographical boundaries without the proper tools. Today, Life Sciences companies are typically amalgamations of countless systems and applications as a result of multiple mergers and acquisitions. Yet content management via spreadsheet and collaboration via email is still the norm—time-consuming, fault-prone methods that limit visibility and lack proper security for intellectual property. Document review and approval processes managed through email or other linear collaboration systems are cumbersome and inefficient. Reviews are often slow because only one person at a time can review, comment on and approve documents.

True collaboration can also be out of reach because companies lack centralized visibility into the work of external partners, such as the status of R&D projects and manufacturing details needed for compliance purposes. At the same time, primary authors are typically unable to see who has reviewed documents (and when), and who has signed off on them, preventing them from tracking progress and finalizing documents with confidence. When documents are circulated using email or other methods outside the system, the audit trail is incomplete.

For these reasons, Life Sciences companies need to drive new efficiencies in document authoring, review and approval processes. For example, they need to consider a content management solution that transforms the process of authoring submission documents into a highly efficient, workflow-driven process. Workflows can not only guide authors through the content development process, but also push documents to the right contributors and reviewers at just the right time.

Equally important, a content management solution should allow multiple contributors to make edits, changes and/or annotations to documents simultaneously, for much faster document creation and review. Ideally, the primary author needs access to a single copy of a document with all participants' input, and then can review, accept or reject edits as appropriate.

These types of incredibly powerful, yet simple innovations can expedite an authoring, review and approval process spanning both internal and external partners.

EFFICIENT DOCUMENT MANAGEMENT FOR FASTER, EASIER SEARCH

The complexity and scale of the information required for new-product applications and submissions seems boundless today. Regulators demand that you include everything from data about nonclinical and clinical trials, raw materials and manufacturing processes, to information about products, worker safety experience and labeling—and that's just to start. Adding to this complexity is the enormous volume of documents and interactions that must be managed across a vast network of geographically distributed vendors, employees, test sites and departments involved.

In short, R&D solutions will need to make it faster and easier for authors and submissions professionals to find applicable documents. By streamlining the planning, tracking and maintenance of submission-related documentation, the right R&D solution can speed up orchestration of submissions, always based on the most authoritative sources.

At the same time, companies need to support professionals' demanding search, navigation and browsing requirements. For example, authors should be able to search archives and documents across one or more repositories, efficiently leveraging prior effort to avoid costly rework and wasted time. And once documents are finalized, submissions professionals need fast, intuitive document search and retrieval tools for quicker submission assembly. This can be enabled by a solution that offers faceted

navigation and robust filtering and grouping capabilities to effectively reduce the document lists shown to users based on the categories they select.

ENTERPRISE MOBILITY

Today's workforce demands mobile-friendly tools with an intuitive interface that allows them to review, approve and author documents while on the go. Some pharmaceutical companies are using tablets to provide standard operating procedures (SOPs) on the manufacturing floor, as well as to give people convenient, secure access to controlled documents and workflow tasks to accelerate processes. Modern systems and tools should require little to no training to achieve competency and provide role-based access to documents. Mobile applications designed with the specific audience in mind prove to be the most effective. For example, a simplified user interface for reviewer and approver is easily deployed and quickly adopted by occasional users, allowing them to complete workflow tasks with the ability to comment on the content.

AGILITY

In truth, most traditional content management systems are too rigid for the dynamic nature of Life Sciences companies today. Regulatory requirements vary by country and region and are prone to constant change. You should be able to make small system changes via configurations rather than coding, with automated documentation of the delta between the old and the new—and without incurring significant delays and costs.

Further, today's Life Sciences organizations need to maximize their resources and budgets in a way that enables innovation, seamless business processes and quick responses to changing business needs. You need flexibility and agility as well as security, privacy and access control. Deployment should meet your specific needs—whether private, public, hybrid cloud or traditional on premise.

A FOUNDATION FOR THE FUTURE

Competing in Life Sciences today, given the rapid pace of change and constant pressure to accelerate time to market, requires organizations to rethink, recalibrate and even transform their traditional approaches to doing business. Improving process efficiencies is essential. Establishing a path toward excellence in regulatory submissions is one of the ways to achieve substantial efficiencies throughout the organization and beyond. Adoption of a complete enterprise-wide solution helps to increase visibility across the organization, adds efficiencies when working with internal and external partners, and promotes overall compliance.

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