

WHITE PAPER

A path to excellence in the global regulatory submissions process

Driving efficiency in research and development



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Introduction

Streamlining the regulatory submission process is essential to getting products to market faster. 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. Without efficient and authoritative global systems, communication between corporate headquarters and local affiliates is difficult. While sponsors are ultimately responsible for the safety of the products available on 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 access 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—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 that 40 percent of affiliate time is spent coordinating and managing regulatory information. Approximately 25 percent of that time is spent on unproductive activities such as data re-entry.

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, adaptability and bi-directional communications. Participants in the authoring process need solutions that both support reliable, seamless and simultaneous collaboration across geographical locations. Achieving this requires a unified approach to integrate or consolidating content management systems and applications functioning in silos.

As a leader in Enterprise Content Management for the life sciences industry, OpenText offers a valuable perspective on current trends and real needs. This white paper explores what makes the regulatory submissions process so unique and challenging, and how innovative solutions can better support the process.

Envisioning a better way

Life sciences companies need to enable regulatory professionals to streamline, standardize and add transparency to authoring and submissions work. The right approach will make it easier for organizations to answer fundamental questions on how to:

- Collaborate more efficiently with internal and external partners, while reducing errors
- Find and leverage previous work that is still relevant and useful
- Shorten the document authoring and approval process and streamline workflows
- Help those who participate in the process infrequently reduce errors and increase efficiency
- Gain full visibility into the status of submissions authoring, review and approvals
- Ensure complete, accurate and compliant submissions that keep up with changing regulatory requirements for different markets
- Determine which submissions are affected by regulatory and other changes
- Support work with local affiliates in global environments



From a functional perspective, what innovations and new thinking are needed to transform? 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 can be submitted to regulatory agencies, it must also be shared with the regulatory department. 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, 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.

A robust content repository is needed to manage 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.

Those documents become the single source of truth across the enterprise. The head office can distribute them to all regional affiliates while enabling them to create local content based on regional requirements. They can communicate the local content back to the head office to help maintain compliance, reduce workloads and improve the efficiency of the submission preparation process.

Standardization and best practices

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

Using standards and pre-configured document inventories, terminology and vocabularies driven by reference models makes the process easier, even for occasional users. This approach also simplifies sharing of data across organizational boundaries and systems, and makes it 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. Being able to automatically populate ICH-compliant templates with content based on document properties and auto-filing 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.

With these innovative features, even inexperienced users can effectively author and manage submission-ready documents, and 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. 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. Primary authors are also typically unable to see who has reviewed documents, when they were reviewed 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 can access a single copy of a document with all participants' input and then review, accept or reject edits as appropriate.

These types of powerful, yet simple innovations can expedite an authoring, review and approval process including 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 seem boundless. Regulators demand that organizations include data about nonclinical and clinical trials, manufacturing processes and the raw materials that are needed, as well as worker safety experience and labeling information. 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.

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 to efficiently leverage prior effort and avoid costly rework and wasted time. Once these documents are finalized, submissions professionals need a fast, intuitive document search and retrieval tool with faceted navigation and robust filtering and grouping capabilities.

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, occasional users can quickly adopt a simplified user interface for reviewer and approver, allowing them to complete workflow tasks with the ability to comment on the content.



Agility

Most traditional content management systems are too rigid for the dynamic nature of today's life sciences companies. Regulatory requirements vary by country and region and are prone to constant change. Organizations should be able to make small system changes via configurations rather than coding, with automated documentation of the difference between the old and the new—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. They need flexibility and agility as well as security, privacy and access control. Deployment should meet specific needs—whether private, public, hybrid cloud or traditional on-premises.

A foundation for the future

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 this throughout the organization and beyond. Adoption of a complete enterprise-wide solution helps increase visibility across the organization, adds efficiencies when working with internal and external partners promotes overall compliance and allows the organization to succeed in today's life sciences market.

OpenText™ Documentum™ for Life Sciences

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