IMPROVING EFFICIENCY AND SPEED ACROSS THE EXTENDED ENTERPRISE

Optimizing Regulatory Information Management (RIM) in Life Sciences

EMC PERSPECTIVE

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INTRODUCTION

Life Sciences companies are under pressure to balance innovation with cost-cutting measures—across the enterprise—while ensuring that the drugs they bring to market are managed in a patient-centric way. They need to reduce the costs of regulatory operations and speed up health agency approvals to accelerate time to market. And, to compete in a global marketplace, they need to be able to incorporate global regulatory intelligence into business processes and do a better job of maximizing existing assets to expand reach into emerging markets. Process efficiency is paramount.

Yet even after making significant strides in establishing cross-divisional regulatory information management (RIM) programs, many companies are still not meeting their efficiency goals. Despite a diverse range of tools in place to help analyze, interpret and share information, what is typically missing is a coordinated effort across the enterprise supported by integrated systems for regulatory operations. Processes span a myriad of disjointed systems, exacerbated by mergers and acquisitions and an extended enterprise encompassing global partners. Operational complexity reigns.

According to Gens and Associates, the evolution of RIM over the years has resulted in 16 separate capabilities supporting global regulatory activities[1]. In many cases, global affiliates are involved in a number of these critical activities—notably, submission planning and tracking, submission-ready document management, health authority communications, labeling and product registration. Yet accessibility and usability present a problem, particularly for affiliates and infrequent users.

Clearly, effecting convergence of these processes, reducing complexity and improving the user experience are all essential to improving efficiency, as well as data quality, accuracy, compliance and visibility.

[1] Gens & Associates, Next Generation Regulatory Information Management and Intelligence: Strategy, Investments, and Status, Winter Edition, 2015, page 24

THE NEED FOR A STRATEGIC, ENTERPRISE-WIDE RIM STRATEGY

With these complex dynamics in play, Life Sciences companies must adopt a big-picture RIM strategy that drives smarter, faster and lower-cost decision making. Evolutionary shifts in the industry require a willingness to transform the business, both to stay abreast of the ever-changing environment and to anticipate the future. A key objective for the next-generation Life Sciences enterprise is rethinking and recasting the core set of regulatory systems with an intelligent, interconnected RIM framework. What is needed as part of this framework is an enterprise content management (ECM) solution that facilitates and supports information access, sharing, visibility and integrates seamlessly across the extended enterprise—for both internal and external participants.

Today, according to the Gens report, RIM is being viewed as "strategic asset that needs to be managed as a vital part of an organization's business infrastructure,"[2] not as a tactical necessity to support compliance activities. Compliance is a given; executives are now expecting RIM initiatives to drive efficiency and productivity across the organization. In fact, over half of Life Sciences industry survey respondents had a cross-divisional RIM program in place, and this increased to 77% for the larger multi-national companies. That means that companies without a RIM strategy in place are already behind the competition.[3]

Let's take a look at the foundation for a successful RIM initiative.

A SINGLE PLATFORM FOR REGULATED CONTENT MANAGEMENT ACROSS DOMAINS

Fortunately, the evolution of RIM systems has given rise to solutions that offer a new approach, with an enterprise information architecture serving as a single authoritative source across different steps in regulatory processes. Let's look at one component of the RIM platform and discuss innovations we should expect from the modern solution: a content management system. Content management is a vital component of any RIM initiative. After all, content is associated with the drug starting at discovery and stays with it throughout its lifecycle.

In an enterprise-wide RIM platform, the content management component should provide functionality that enables documents in one domain to be used in another. Instead of operating in silos, importing and exporting from one system to another, it is far more efficient to link to the approved, current version in the clinical system, for example, directly from the R&D solution. Documents for different functional areas can be managed in a single repository, enabling business users to treat documents as a single source of truth for various purposes. With an information architecture based on a common data model, such as the Drug Information Association (DIA) Electronic Document Management (EDM) and Trial Master File (TMF) Reference Models, this single repository enables cross-repository searches and linking.

Data and documents can be entered just once and, for those with the proper permissions, are accessible in any context. This approach minimizes discrepancies and uncontrolled copies, resulting in timely, accurate, accessible information. Organizations can respond faster to product changes, compliance concerns or health authority requests.

[2] Ibid., page 7.
[3] Ibid., page 4

A STREAMLINED PROCESS FOR CREATION, REVIEW AND MANAGEMENT OF SUBMISSION DOCUMENTATION

As outsourcing became a common practice for Life Sciences organizations, they have shifted the emphasis from cost reduction to better management of organizational headcount and workload levels.[4] Achieving this objective requires a streamlined process for managing submission documentation across the extended enterprise.

By leveraging industry-standard dictionaries, taxonomies and object models with a template-based authoring process, organizations can boost author productivity and collaboration. Today's solutions offer role-based interfaces designed for simplicity, even for occasional users. Authors can use a predefined inventory of industry-standard documents that are automatically linked to templates compliant with International Committee on Harmonization–Common Technical Document (ICH-CTD), adding efficiency to submission-ready document creation. Reusable registration forms facilitate data standardization and auto-indexing to reduce error-prone manual data entry in preparation for submissions.

Collaborative authoring tools for simultaneous editing can streamline review and approval processes. Users can quickly identify submission-related documentation using faceted navigation, based on ICH-CTD standards, that identifies and classifies documents.

This approach does more than drive efficiencies in regulated content management. With tight integration between content management and other RIM components, you can also achieve efficiencies through automatic transfer of metadata and content. For example, information entered in a registration tracking tool can be automatically pushed to a content management system for consumption to facilitate a single source of truth and reduce redundant data entry. Similarly, an automated process can properly link a document in a submission outline in the publishing tool to eliminate manual processes. The results: shared and high-quality data, streamlined workflow, along with accuracy and completeness of submission-ready documentation, with all required content elements included.

SEAMLESS INFORMATION SHARING BETWEEN HEADQUARTERS AND LOCAL AFFILIATES

While sponsors are responsible for the accuracy of submission content—and ultimately, product quality and safety—visibility into regulatory activities continues to be a challenge for many Life Sciences organizations. What has been submitted by regulatory affiliates to the health authority? Is the data submitted accurate and in the best interests of the company?

In turn, affiliates often lack access to critical submission documentation. They often maintain their own systems for managing registrations and submissions because security barriers prevent connection to the central system, or because the central system is not compliant with their infrastructure. This is a recipe for inefficiency, and a significant drain on time and resources. In fact, in his research, Steve Gens found that 40% of affiliate time is spent coordinating and managing regulatory information, with approximately 25% of the time spent on non-value-added activities such as data reentry.

Organizations must have confidence in the quality of product registration information maintained in global systems, while ensuring that affiliates have information access, flexibility, adaptability and bidirectional communications. Today's solutions offer a way to ensure reliable, seamless and simultaneous collaboration between people separated

[4] Ibid., page 18.

by geographical and organizational boundaries, supporting efficient information sharing including content, internal and Health Authority communications.

BEST PRACTICES FOR A RIM SOLUTION

Many organizations today are establishing best practices based on the concept of a Global Regulatory Index (GRI), also known as a core dossier or corporate package. The objective is to create a package of all sponsor-approved submission content for a given product at any point in time. The content is created and approved by the sponsor, updated on a routine basis and released to the affiliates. The common content can be used anywhere in the world for submissions, based on the approved GRI. The GRI is structured using a "virtual document"—essentially, a document composed of other documents—that helps organize multiple documents created by authors from different functional areas. This way, certain functions can be performed on a large number of documents in a single action.

Another key best practice is ease of use. Today's RIM solutions provide intuitive, personalized, role-based views that enable workers to complete their routine tasks simply and efficiently. Modern mobile applications can enable them to work on smartphones or tablets even when they are traveling or in the field.

True flexibility also extends to deployment options of the RIM solution. Today's Life Sciences organizations need seamless business processes and quick responses to changing business needs, while ensuring that their security, privacy and access control requirements are met. There is no one-size-fits-all deployment solution. For example, a public cloud might be an option when ease of access for external partners is paramount, while on-premise or private cloud deployment might be the best choice when IP protection is a concern. Best practices mandate choice in deployment options.

ARCHIVING FOR A COMPLETE VIEW OF REGULATORY ACTIVITY

Once products are approved and commercialized, Life Sciences organizations must still keep current, complete records of all documents associated with regulatory submissions for each product in each market—as well as related agency communications including emails, meeting minutes and phone records. Sponsors need easy access to regulatory correspondence linked with the submission, and the ability to quickly search and retrieve archived submissions and associated documents to respond to queries.

Today's solutions enable archiving of published output in a secure and compliant repository. Correspondence can easily be uploaded and viewed in conjunction with the related regulatory activity.

With support for standard Electronic Common Technical Document (eCTD) structure, regulatory submissions can be automatically stored while retaining deep folder structures exactly as they were submitted to the regulatory agency—enabling navigation and viewing of the full submission lifecycle. Additionally, these solutions support searching for archived submissions via faceted navigation or based on metadata properties such as product, country, manufacturer, submission type or date.

Further, additional efficiencies can be achieved with advanced capabilities such as chronological log creation for regulatory activities and the ability to view related or grouped submissions.

HOW TO EVOLVE TO A BEST-PRACTICE RIM SOLUTION

Most organizations, largely because of mergers and acquisitions, maintain multiple systems that are often overlapping or even exactly the same. To complicate the situation even more, legacy systems are typically highly customized and function as silos impeding efforts to simplify and unify regulatory processes.

Today's solutions are designed based on industry standards and provide technical advantages, with simple configurations that allow organizations to stay current with the latest regulatory requirements. Additionally, current solutions are enabled to support integrations that add efficiencies to end-to-end regulatory processes and activities.

Best practice is to choose a RIM solution that provides a single authoritative source for regulated content, integrating all key activities, including:

- Submission planning with regulatory intelligence
- Registration tracking
- Creation, review and approval of submission-ready and supporting documentation
- Search and retrieval of archived submissions and associated correspondence
- Control of quality and manufacturing documents, with automated workflows and compliance support

ELIMINATING OPERATIONAL COMPLEXITY

In short, streamlining processes, achieving enterprise-wide efficiencies, boosting productivity and supporting regional affiliates are all essential elements for Life Sciences organizations today, whether global multinational or midsize company. Choosing solutions that provide an authoritative source for regulated content and that support a flexible, integration-enabled RIM solution is fundamental to making operational complexity a thing of the past.

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