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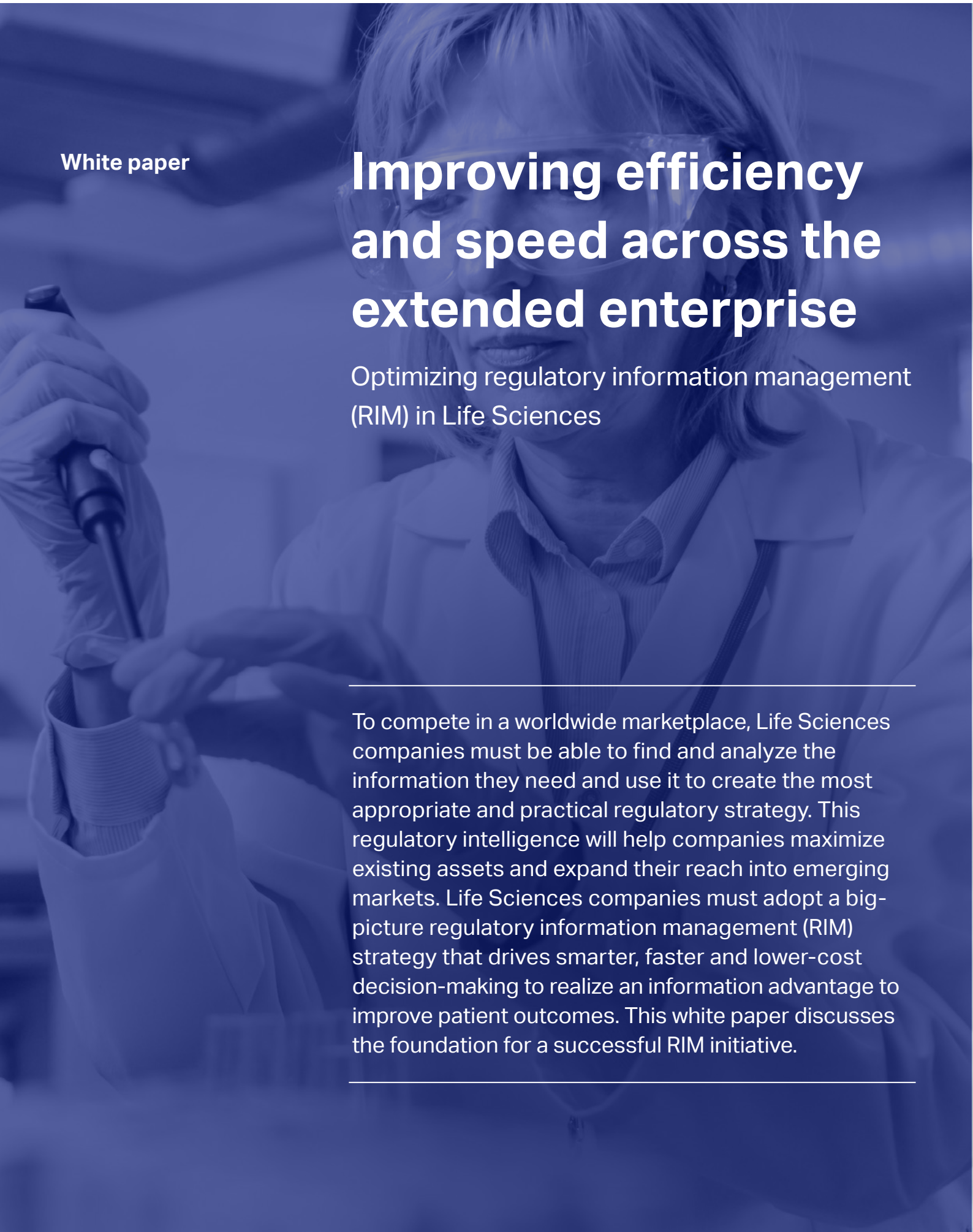
White paper

Improving efficiency and speed across the extended enterprise

Optimizing regulatory information management (RIM) in Life Sciences



To compete in a worldwide marketplace, Life Sciences companies must be able to find and analyze the information they need and use it to create the most appropriate and practical regulatory strategy. This regulatory intelligence will help companies maximize existing assets and expand their reach into emerging markets. Life Sciences companies must adopt a big-picture regulatory information management (RIM) strategy that drives smarter, faster and lower-cost decision-making to realize an information advantage to improve patient outcomes. This white paper discusses the foundation for a successful RIM initiative.

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Introduction

Life Sciences companies are under pressure to balance innovation with cost-cutting measures, while ensuring the products they bring to market to improve patient outcomes 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 use global regulatory intelligence to inform their business processes and maximize existing assets to expand their 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 to help analyze, interpret and share information, companies are typically missing a coordinated effort across the enterprise supported by integrated regulatory operations systems. 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, regulatory information management (RIM) is one of the highest priority investment areas in Life Sciences R&D today. It is driven by the need to greatly improve the efficiency of regulatory activities globally, currently averaging 43 percent across 18 RIM capabilities, and manage regulatory information as a true enterprise asset.[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.

Converging these processes, reducing complexity and improving the user experience are all essential to increasing efficiency, as well as data quality, accuracy, compliance and visibility.

The need for a strategic, enterprise-wide RIM strategy

With these complex dynamics, 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 and visibility while seamlessly integrating across the extended enterprise—for both internal and external participants.

Today, according to the Gens and Associates report, RIM is being viewed as an enterprise asset, not as a tactical necessity to support compliance activities. In fact, for most, compliance is assumed as progressive organizations look for value in efficiency, productivity, speed and resource re-allocation, along with a real time to realize these benefits.[2]

As for investments, in 2019-2020, companies, regardless of size, consider improving data management, along with standards and connections to other functional areas, a major priority. Another clear challenge for most regulatory organizations is having a mature and disciplined continuous improvement program that is driven by performance metrics.[3]

This white paper will next explore the foundation for a successful RIM initiative.

1 Gens & Associates, The Promise of Enterprise RIM – What's Slowing the Innovation Potential?, 2019.

2 Gens & Associates, 2018 World Class RIM: Connections to Product Chance, Supply Release and QMS, Fall Edition.

3 Ibid.

Single platform for regulated content management across domains

Fortunately, the evolution of RIM systems has brought solutions that offer a new approach, with an enterprise information architecture serving as a single authoritative source across different steps in regulatory processes. Take one component of the RIM platform and the innovations we should expect to see from the modern solution—a content management system. Content management is a vital component of any RIM initiative. After all, content is associated with a product starting at discovery and staying with it throughout its lifecycle.

In an enterprise-wide RIM platform, the content management component should enable documents in one domain to be used in another. Instead of operating in silos that import and export from one system to another, it is more efficient to link to the approved, current version in the clinical system, for example, directly from an 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.

Streamlined process for creation, review and management of submission documentation

By optimizing processes, organizations can reduce cycle time and cost while improving quality. 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 the International Committee on Harmonization-Common Technical Document (ICH-CTD), making it easier to create a submission-ready document. 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, which 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 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 and streamlined workflows, along with accuracy and submission-ready documentation, with all required content elements included.

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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 have regulatory affiliates submitted 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, Gens & Associates found that 40 percent of affiliate time is spent coordinating and managing regulatory information, with approximately 25 percent of the time spent on non-value-added activities, such as data re-entry, verifying and finding information.[4] In fact, the most time consuming activities are verification and finding information, not re-entry.

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

4 Gens & Associates, Next Generation Regulatory Information Management and Intelligence: Strategy, Investments, and Status, Winter Edition, 2015.

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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," which is essentially a document composed of other documents. This helps organize multiple documents created by authors from different functional areas, allowing certain tasks to 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. With modern mobile applications, they can 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. Life Sciences organizations need seamless business processes and quick responses to changing business needs, while meeting their security, privacy and access control requirements. 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-premises 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, with advanced capabilities, users can view related or grouped submissions or create a chronological log for regulatory activities.

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.

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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. They also support integrations that make end-to-end regulatory processes and activities more efficient.

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, whether global multi-national or mid-size company. Choosing solutions that provide an authoritative source for regulated content and support a flexible, integration-enabled RIM solution are fundamental to making operational complexity a thing of the past.

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