WEBINAR SUMMARY

July 22, 2020

Pink Sheet
Informa Pharma Intelligence

Meeting the Challenges of Regulatory Information Management

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KEY TAKEAWAYS

- Managing regulatory data and information is challenging for the life sciences industry.
- Automation is transforming regulatory information management, reducing operational costs and increasing efficiency.
- Regulatory intelligence is a crucial component of regulatory information management (RIM) systems.
- RIM systems must be flexible enough to support either a modular approach or end-to-end platform implementation.
- Optimized approaches to compliance challenges require cross-functional integration across regulatory, safety, and quality teams.
- IQVIA RIM Smart delivers heightened speed, accuracy, and efficiency through intelligent automation.

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OVERVIEW

Given the explosion of pharmaceutical products, data, and regulatory requirements across multiple geographies, life sciences companies need better ways to manage and streamline regulatory information. Manually handling commitments, correspondence, publishing, and submissions is obsolete.

Regulatory information management (RIM) systems combine automation with regulatory intelligence to increase regulatory compliance speed, improve efficiency, and reduce operational costs. IQVIA RIM Smart offers a platform for organizations seeking cross-functional integration, as well as deployment flexibility.

CONTEXT

IQVIA's Richard D'Mello and Shylendra Kumar discussed challenges associated with RIM systems, how RIM has evolved over time, and how organizations can build a RIM system that meets their needs.

KEY TAKEAWAYS

Managing regulatory data and information is challenging for the life sciences industry.

Three main obstacles to efficient regulatory data management across organizations, products, and processes are:

1. **Staying current.** The volume of regulations worldwide has grown significantly in recent years. Since 1998, the FDA has released over 2,000 new or modified regulations. In the span of just two years, China has introduced the equivalent of over 30 years of FDA regulation. Keeping up to date with the evolving regulatory landscape across the globe is a significant challenge.
2. **High administrative burden.** According to industry research, 53% of global life sciences CEOs consider industry regulations to be a top disruptive business trend. As the number of new product launches grows, regulatory professionals have found that regulatory compliance means significant administrative burden stemming from increasing manual tasks.
3. **Manual, high-touch, repetitive operational work.** One multinational pharmaceutical company with over 2,000 products marketed in over 150 countries employs more than 1,500 regulatory staff across 80 geographies. This team spends 60% of their time on low-level activities.

The management of regulatory information has evolved from paper-based systems to today's age of automation.

When it comes to regulatory information management (RIM), the life sciences industry has come a long way over the last 20 years. The last two decades can be divided into four periods:

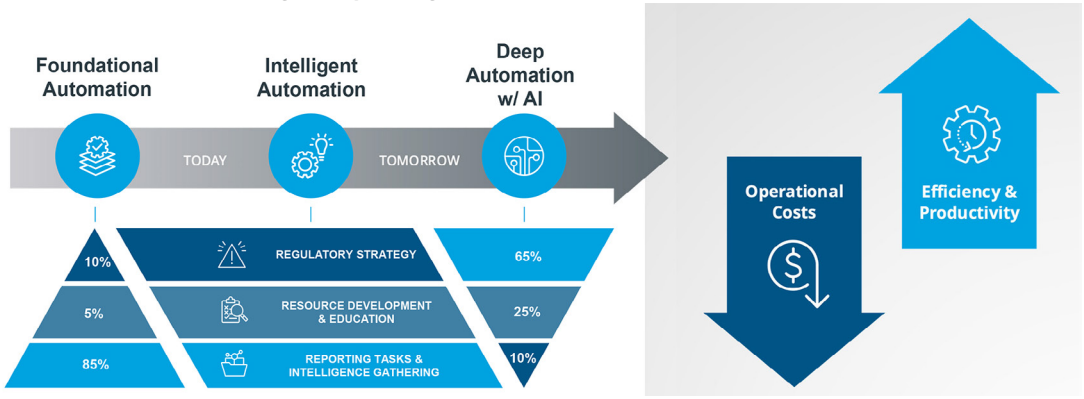
Period	Description
Pre-Digital Era	Twenty years ago represented the "Dark Ages" for regulatory information management. RIM systems didn't exist. Submissions were primarily paper based and regulatory intelligence was obtained from subject matter experts.
Digital Transformation	This era introduced electronic document management systems (eDMS), electronic common technical document (eCTD) publishing, and spreadsheet tracking. On-premise RIM systems emerged.
SaaS Era	Organizations began to adopt cloud technology. Integration with document management systems improved, as did the collection and housing of regulatory intelligence.
Age of Automation	In today's age of automation, RIM systems automate burdensome, manual tasks. The best systems include built-in intelligence and precursory artificial intelligence (AI).

Automation is transforming regulatory information management, reducing operational costs and increasing efficiency.

Three concepts are driving innovation in RIM today: automation, regulatory intelligence, and the end-to-end RIM system. The life sciences industry, as well as IQVIA, is on a journey towards deep automation that enables substantial workload efficiency gains.

Intelligent automation is replacing high-touch, manual, repetitive tasks. Organizations are using automation gains to further develop their teams' core competencies in areas such as regulatory strategy. They are increasing the productivity of their regulatory teams and focusing them on more value-added, strategic activities. The key to success is leveraging deep automation and intelligence to drive decision making and workflow initiation.

Figure 1: Automation Drives Regulatory Management Transformation

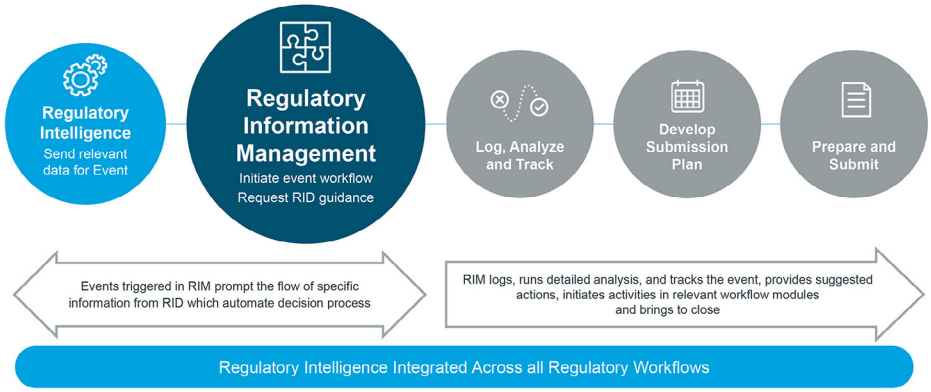


> Our aim is to enable regulatory professionals to spend more time on activities that really matter, while simultaneously reducing operational costs.
>
> *Richard D'Mello, IQVIA Integrated Global Compliance*

Regulatory intelligence is a crucial component of RIM systems.

Regulatory intelligence must be a proactive driver for all regulatory processes. IQVIA RIM Smart has been built with this concept in mind. When regulatory guidance changes occur, that information is automatically gathered from the regulatory intelligence database and passed to IQVIA RIM Smart. This initiates a process and drives it to completion within a single platform. Regulatory intelligence can be applied to any type of regulatory guidance change or new requirement, whether it is a change to technical specifications for dossiers or a change in reporting frequency.

Figure 2: Regulatory Intelligence Proactively Drives RIM Automation



RIM systems must be flexible enough to support either a modular approach or end-to-end platform implementation.

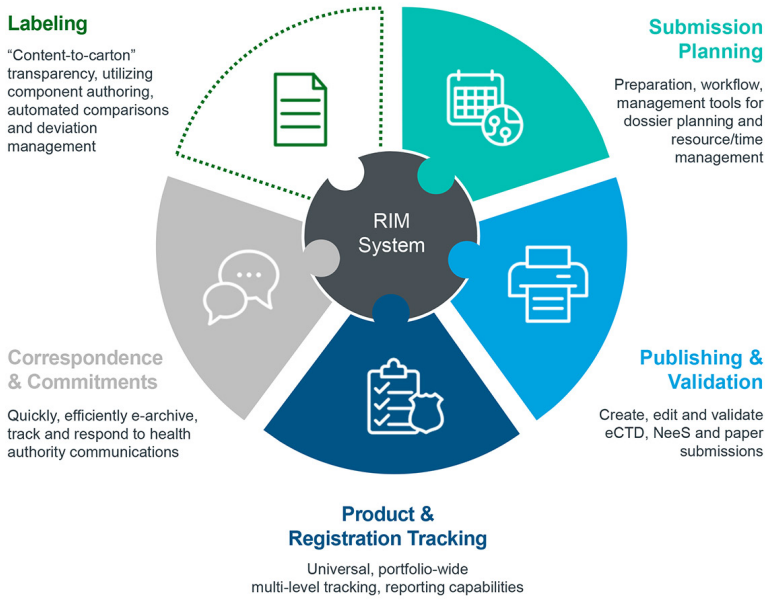
The life sciences industry is divided about the best approach for implementing RIM systems. In 2018, a Gens & Associates RIM survey found that 75% of organizations wanted to deploy an end-to-end solution. The 2020 survey results indicated, however, that this number had decreased to 55%.

IQVIA recognizes that RIM solutions must be flexible enough to connect with existing systems to support a modular approach, as well as provide a true end-to-end platform. IQVIA RIM Smart is a fully integrated, cloud-based, end-to-end regulatory information management solution for life sciences organizations. It integrates with existing content and document management systems, enabling optimal flexibility for organizations. IQVIA RIM Smart leverages automation, artificial intelligence, and natural language processing. It also incorporates regulatory intelligence into workflows.

The system has five core modules: submission planning, publishing and validation, product and registration tracking, correspondence and commitments, and labeling. Each module can be implemented individually in a hybrid solution or as part of a single, connected end-to-end system.

Additionally, RIM Smart's embedded regulatory intelligence database includes up-to-date, country-level reporting requirements. The content management functionality automates the creation of compliant, submission-ready content (eCTD) that is synchronized with master data management (MDM).

Figure 3: IQVIA RIM Smart Modules



A viewer and archive module enables users to read and navigate eCTD, non-eCTD electronic submissions (NeeS), and other e-submissions in varying views.

Optimally meeting compliance challenges requires cross-functional integration across regulatory, safety, and quality teams.

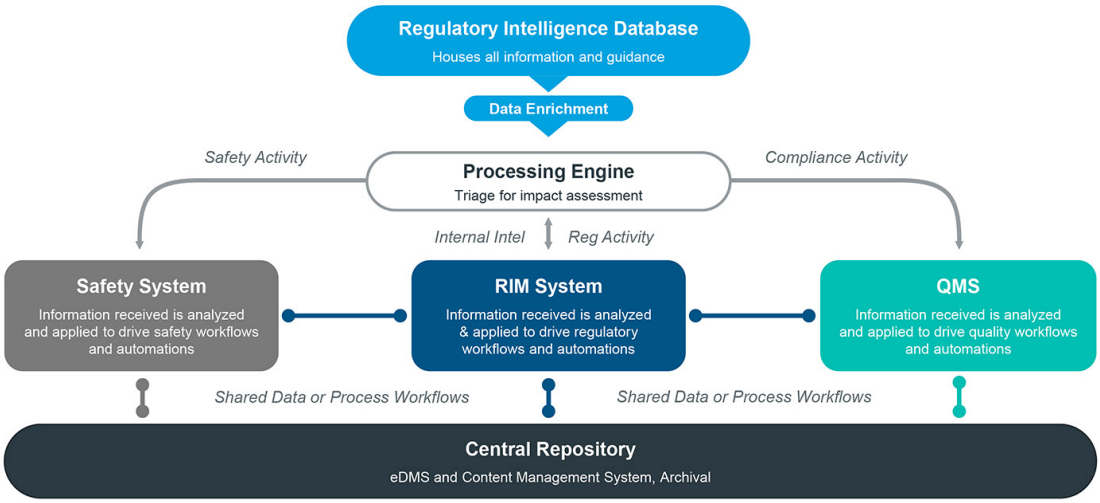
When selecting and implementing a RIM system, organizations must recognize the need for cross-functional integration. The regulatory, safety, and quality functions share product information, as well as submission and reporting information, regulatory intelligence requirements, content, and documents. Yet, challenges still exist due to organizational silos and disparate systems and processes.

Historically, most RIM systems have not been built with cross-functional integration in mind. As demand for cross-functional connectivity increases, however, RIM system development must also evolve. IQVIA is investing heavily in a compliance ecosystem that enables cross-functional integration, having built connectivity between the RIM Smart system, IQVIA's comprehensive safety Vigilance Platform, and IQVIA's SmartSolve® quality management system. This integrated approach increases speed and efficiency, while improving accuracy and compliance.

In a cross-functional system, two factors help break down silos and enhance interconnectivity:

1. **A common central document and content management repository.** Each independent system must have access to the information required to drive processes and track milestones. It needs to pull content from and archive finalized content back to the centralized repository in a seamless way.
2. **A common regulatory intelligence layer.** This layer alone is not enough, however. Organizations must be able to enrich the data and send it through a processing engine that leverages AI and natural language processing to assess the impact of changes, determine outcomes, and route information to the relevant destination. The processing engine may also initiate activities and workflows in the RIM system or other systems automatically.

Figure 4: Building Bridges Within Organizations by Using Existing Technology More Efficiently



Two use cases illustrate how IQVIA RIM Smart enhances operational efficiency for life sciences companies:

1. Improving publishing cycle times through automation.

A submission may be ready to go to regulatory agencies, and then last-minute changes are made to the document. Pages may be added or deleted, or there may be a change to a single sentence or word. Users can leverage the system's built-in intelligence to analyze and identify desired changes in the revised document. When users replace a document in IQVIA RIM Smart, the system gives the option to migrate links and bookmarks from the previous document version to the revised one, which is a major time saver. It is easy to finalize the revised submission, publish it, and send it to the reviewers for approval in a matter of minutes.

2. Managing the chemistry, manufacturing and controls (CMC) change control process.

Manufacturing changes occur very frequently. For example, when a pharmaceutical company changes the shelf life of a product, it must inform all relevant regulatory agencies and request approval before updating labels and the associated manufacturing processes. This can take several weeks or months—especially if multiple countries are involved. Companies need country-specific intelligence, guidance, and specifications to make these decisions and chart the appropriate pathways. IQVIA RIM Smart reduces the process to hours or days. It helps with impact analysis, identifying the applications affected by the change. The system identifies proposed actions based on the most recent regulatory information in the regulatory intelligence database. Once the automated workflows begin, teams simply track processes and status updates.

> IQVIA RIM Smart's intelligent automation enhances efficiency and reduces timelines significantly. One company said their overall reduction in processing time was 60%.
>
> *Shylendra Kumar, IQVIA Technology Solutions*

IQVIA RIM Smart delivers efficiency through intelligent automation.

IQVIA RIM Smart is a subscription-based SaaS solution. The system is accessible from anywhere in the world with an internet connection. Users interact with a customizable dashboard that provides instant access to key areas of interest, assigned tasks, and reports.

BIOGRAPHIES

Shylendra Kumar

Director, Product Offering and Development, IQVIA Technology Solutions

As Director of Product Offering and Development, Shylendra Kumar is responsible for leading the design, development and delivery of regulatory technology solutions for IQVIA. He focuses specifically on strategic innovative solutions that drive efficiency through intelligence and automation. Kumar received his MPH (Epidemiology and Biostatics) degree from Boston University and an MA (Social Sciences) degree from Bangalore University.

Richard D'Mello

Senior Director, Commercial Strategy and Operations, IQVIA Integrated Global Compliance

As Senior Commercial Strategy and Operations Director for IQVIA Integrated Global Compliance, Richard D'Mello is responsible for driving the growth of IQVIA's Safety, Regulatory, Quality and Commercial Compliance business. This includes establishing and governing strategic initiatives and identifying innovative technology and services solutions that meet the needs of customers. D'Mello obtained his PhD in Neuroscience from University College London and a Bachelor of Science (Hons) in Biomedical Science from Kings College London.