Regulatory information management (RIM)

Optimizing regulatory submission processes for effective information management.

Regulatory affairs organizations experience significant challenges in managing all the information and correspondence associated with global submissions and product registrations. In many instances, labor-intensive, manual processes are in place, and information is organized in spreadsheets or costly, custom systems.

In addition to these inefficiencies and costs, outsourcing partners need to be managed and the appropriate regulatory filings need to be updated and approved by health authorities prior to implementation of manufacturing change controls to ensure compliance.

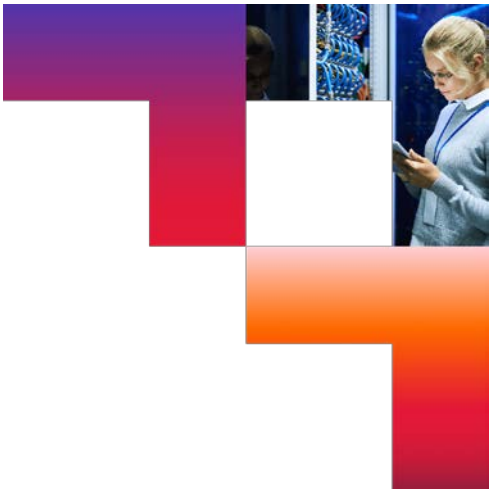
Partnering with regulatory optimization experts who know the latest leading industry standards, technologies and process efficiencies at the start of the initiative can help ensure that the best procedures for planning submissions, authoring, review/approval, managing health authority correspondence/ commitments, integrating with change control processes, etc., are implemented.

Achieving your RIM vision: CGI's RIM framework

CGI has extensive experience working with clinical trial sponsors and CROs to understand their regulatory information management challenges and help them successfully achieve an optimized RIM vision.

We have developed a comprehensive, leading practice RIM framework to facilitate the development of a future state RIM strategy and roadmap for managing regulatory information across the organization. Our framework addresses the people, process, information and technology aspects of the RIM vision, and ensures alignment among executive and business leaders.

Our strategy practitioners leverage this framework to provide a comprehensive view of the current environment, a vision for the future based on leading practices tailored to your needs, and a roadmap for getting there. The roadmap provides a path forward to more efficiently and effectively:



Benefits of an optimized RIM strategy

Below are just some of the benefits that can be achieved by implementing RIM capabilities and optimizing submissions processes.

- Faster time to market via more efficient and effective submission and correspondence management
- Greater business productivity resulting from having more time to focus on other activities and simplified business process interactions with external service providers
- Increased visibility into regulatory activities globally (e.g., what submission was filed in what countries, what commitments were made and when are they due, health authority correspondence, changes in regulations or interpretations, etc.)
- Enhanced compliance with product registrations and more consistent health authority interactions.

- Manage global product registrations and manufacturing changes throughout the product life cycle
- Manage health authority correspondence and commitments
- Plan and manage regulatory submissions, labeling, and promotional materials
- Manage pharmacovigilance and adverse events
- Stay abreast of the latest regulatory intelligence

Addressing the full spectrum of RIM

CGI's RIM framework enables life sciences organizations to automate and streamline processes and establish best practices in:

- Registration management – Efficiently track which submissions have been approved, in what countries, etc.
- Regulatory intelligence – Keep your finger on the pulse of new regulations, what they mean, and what others are doing to address them.
- Labeling management – Manage XML labeling content creation and revisions across versions and countries.
- Pharmacovigilance management – Proactively manage adverse events and report to appropriate stakeholders.
- Submission planning & management – Integrate submission plans with product development plans to reduce time-to-market and improve collaboration and process integration of document authoring, review, and approval.
- Correspondence management – Effectively manage regulatory correspondence and notifications.
- Commitment management – Receive notifications to keep track of regulatory commitments and ensure they are met.
- Promotional materials management – Effectively manage the entire lifecycle of promotional materials from creation through dissemination and retirement.
- Chemistry manufacturing & control (CMC) management – Understand the impact manufacturing changes have on regulatory filings and ensure appropriate approval by health authorities before implementation.

CGI's solution capabilities

Some of the areas where the CGI team can help include:

- Promotional materials management
- eSubmissions/eCTD
- Electronic Trial Master File optimization
- GxP quality systems
- Enterprise content management strategy and implementation
- Big data analytics
- Information governance
- Content migration / cloud readiness
- Content imaging / scanning solution implementation

About CGI

Insights you can act on

Founded in 1976, CGI is among the largest IT and business consulting services firms in the world.

We are insights-driven and outcomes-based to help accelerate returns on your investments. Across hundreds of locations worldwide, we provide comprehensive, scalable and sustainable IT and business consulting services that are informed globally and delivered locally.

For more information

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