

# Regulatory Information Management (RIM)



## Optimize your regulatory submission processes to effectively manage information.

Regulatory organizations face many challenges for managing all the information and correspondence associated with global submissions and product registrations. But by partnering with regulatory optimization experts familiar with the latest industry standards, technologies, and process efficiencies, they can take advantage of the best approaches for planning, authoring, review and approval of submissions, dealing with health authorities, and managing change control processes, among other things.

### Achieve your RIM vision: with CGI's RIM framework

Drawing on extensive experience working with clinical trial sponsors and CROs, CGI has developed a deep understanding of the challenges associated with managing regulatory information. This lets us help you achieve an optimized RIM vision.

We have developed a comprehensive, leading practice RIM framework to facilitate the development of a forward-looking RIM strategy and roadmap for managing regulatory information across an organization. Our framework addresses the people-related, processual, informational, and technological aspects of an RIM vision and ensures the alignment of executive and business leaders.

#### We help you:

- 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
- Keep up with the latest regulatory intelligence



### Benefits of an optimized RIM strategy

#### The achievable benefits include:

- Faster time to market
- Greater business productivity
- Increased visibility of regulatory activities globally (such as which submissions have been filed in which countries, which commitments have been made and when they are due, health authority correspondence, changes in regulations or interpretations, etc.)
- Enhanced compliance with product registrations and more consistent health authority interactions

## Addressing the full range of RIM

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

- **Registration management:** efficiently track which submissions have been approved in which 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 and 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 and control (CMC) management:** understand the impact of manufacturing changes on regulatory filings and ensure appropriate approval by health authorities before implementation

## About CGI

### Insights you can act on

Founded in 1976, CGI is now one of the world's largest IT and business consulting services firms.

We are insights-driven and outcomes-based to help accelerate the 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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