

IQVIA RIM Smart Content Management – Messaging Framework

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High level messages

IQVIA RIM Smart description	RIM Smart is the modern regulatory information management solution built to increase speed, collaboration, efficiency, and visibility across your entire global portfolio, improving performance at a lower cost. Delivered securely in the cloud, IQVIA RIM Smart provides integrated, comprehensive, and intelligent management of the entire regulatory process.
IQVIA RIM Smart Content Management description	IQVIA RIM Smart Content Management is a new module in the integrated RIM Smart suite that empowers users to collaboratively plan, author, review and approve GXP-compliant regulatory documents aligned with the relevant industry standards such as eCTD and CTD. Regulatory professionals use time-saving tools including workflows to orchestrate the submission process more efficiently and intuitively.
RIM Smart Content Management Positioning	For life science companies ranging from emerging biopharma to global organizations, IQVIA RIM Smart Content Management empowers users to collaboratively plan, author, review, and approve regulatory submission content aligned with the relevant industry standards. Regulatory professionals now have a versatile solution for augmented submission assembly content to publish more quickly across the regulatory submission process. Unlike competitive applications that separate regulatory functionality and content in siloes and lack tools for today’s complex requirements, RIM Smart Content Management maintains one global source of authoritative content across an integrated SaaS suite.
RIM Smart Content Management Value Proposition	IQVIA’s RIM Smart Content Management offers regulatory professionals peace of mind through a superior solution for collaborative planning, authoring, reviewing, and approving GXP-compliant regulatory submission content globally. Out-of-the-box integration with RIM Smart Submissions streamlines overall submission management and provides full document traceability by version, local market, and regulatory activity.

Customer pain points	RIM Smart Content Management capabilities and benefits
Tracking versions across multiple SharePoint sites and offline storage and sharing document attachments over email makes it difficult to collaborate and may delay outcomes.	<ul style="list-style-type: none"> • Intuitive dashboard displays active documents, workflows, tasks, and notifications in a single web location. • Multiple workflows with annotations, collaborative authoring, and bulk-importing.
Manual document management, including reconciliation of renditions and relationships, is inefficient. Submission and labeling errors are expensive to correct and wasteful and may expose teams to compliance risks.	<ul style="list-style-type: none"> • Manage regulatory submission documents in accordance with industry standard CTD and eCTD content structures. • Customers control their regulatory documents, reducing the risk of non-compliance.

Pillar themes and messages			
Pillar themes	Essential component of regulatory information management	Collaborate on high-quality submission content with end-to-end visibility	Orchestrate submission processes more efficiently and compliantly
Key messages	<ul style="list-style-type: none"> Built on RIM Smart platform that provides consistency and leverages the core capabilities across the content lifecycle. Out of the box integration with RIM Smart Publishing and Label Management modules for augmented submission assembly. One global repository that eliminates risk and creates higher quality documents. Software as a service architecture manages administration and future proofs with new capabilities. 	<ul style="list-style-type: none"> Pre-built and configurable, task-driven workflows for versioning, review, and approval of document submissions in a GXP-compliant fashion. Improve document quality through better collaboration and transparency among regulatory stakeholders. User-focused interface for document journeys makes it easier and faster to produce submission content. Best practices to assist in the development of submission-ready and compliant documents. 	<ul style="list-style-type: none"> Customers control their regulatory documents, reducing the risk of non-compliance. Manage regulatory submission documents in accordance with industry standard CTD and eCTD content structures. Manage the complete document lifecycle using timelines, relationships, permissions, and renditions. Regulatory-ready with FDA's 21 CFR Part 11 requirements governing electronic records, audit trails, and digital signatures.
Support points	<ul style="list-style-type: none"> Full product metadata synchronized across RIM Smart including regional market and study information. Structured content that is crucial to authoring automation (including translation), submission automation, and general re-use. 	<ul style="list-style-type: none"> Intuitive dashboard displays user activities including active documents, workflows, tasks, and notifications in a single web location. Includes 340+ pre-formatted, global authoring templates. Support for both real-time and asynchronous collaboration among document authors and reviewers. Predefine or create new document views, name and share views, modify by adding and removing criteria easily. Add, search, reply to, and export annotations in shared documents. 	<ul style="list-style-type: none"> Workflow owner has real-time visibility into document contributors, task completion, and risks to timeline. Full real-time traceability into document submission by version, market, and regulatory activity. Monitor system utilization organization-wide with metrics for document creation and updates as well as authors and reviewers.

Differentiators

- Comprehensive activity dashboard with active documents, workflows, counters, tasks, and notifications in a single location.
- A single source of truth on a centrally managed platform for all regulatory documents, artwork, and packaging materials.
- Full product master data synchronized across RIM Smart including regional market and study information.
- >340 pre-formatted, global authoring templates, with automated insertion of pre-configured custom properties into new documents.
- Intuitive user interface results from research by product experience design team into needs of customers in regulatory roles.
- Hosted on the robust and proven Salesforce platform, enabling further integration with other Salesforce-based applications.
- Native integration with Publishing and Label Management modules for augmented submission assembly.

Elevator pitch

IQVIA RIM Smart Content Management provides pharmaceutical companies with a future-proof and intuitive solution for managing regulatory submission content. This solution provides a single source of truth for cross-functional teams to manage evolving submission content collaboratively and efficiently in compliance with industry regulations. RIM Smart Content Management is part of IQVIA's regulatory ecosystem and is integrated with IQVIA RIM Smart's labeling, registrations, and submissions modules. This simplifies regulatory workflows and reduces your team's workload, freeing up time to focus on what matters most – accelerating time to approval to bring breakthrough treatments to patients faster.