IQVIA™ eReg

Create and manage submission-ready documents while ensuring compliance.

STREAMLINE YOUR PROCESS

IQVIA™ eReg is a streamlined solution for creating and managing the documents required by Health Authorities to support new drug applications and submissions worldwide.

IQVIA™ eReg supports document authoring, review, and electronic signature and produces submission-ready PDFs at the required eCTD granularity while organizing content for fast retrieval when preparing submissions.

Produce and Assemble Submission-Ready Content

- Enforces ICH and Health Authority required granularity
- Automatically generates compliant PDFs
- Automatically organizes your documents in a CTD-based structure ready for publishing

Create Compliant Documents

eReg manages your authoring templates and makes sure you only use approved templates that match your document type. You can create a new document in just a few clicks - most metadata is auto-populated.

View Product Dashboards

eReg provides you with a dashboard for each product, summarizing clinical and nonclinical studies, drug product and substance, excipients, and regulatory applications. One click takes you to related documents.

Navigate the Product Dossier

eReg provides multiple navigation options including folder structures and filtered searches. Publishers can quickly locate the content needed for a particular eCTD section or study and drag into a publishing tool.

Work Locally. Publish Globally.

eReg comes configured out of the box for the US, EU, Japan, Canada, Switzerland, Australia, South Africa, Thailand, and Saudi Arabia.

One Click Export

Need to deliver your documents to a publishing partner? eReg allows you to create a zip file with the relevant documents in PDF format (where applicable) to streamline the process.

Review and Approval

It's simple to start or participate in a review or approval workflow. When the electronic signature option is used, approvers are prompted to sign, and after all approvals have been received eReg generates a 21 CFR Part 11 compliant signature page. Workflow initiators can manage their workflows, adding and removing participants and terminating workflows if needed.

Implement Quickly

- Two to four weeks from start to finish
- Training sessions and materials included
- Complete UAT package including URS, Test Plan, Test Scripts, and Test Report

Leverage Our Expertise

IQVIA™ eReg is part of the IQVIA RIM Smart Regulatory Suite and includes the following:

- Correspondence and Commitments
- Publishing & Validation
- Submission Planning
- e-Submission Viewer
- Registration and Tracking
- PDF tools
- Submission Validator

IMS Health & Quintiles are now IQVIA™

IQVIA™ eReg is a streamlined solution for creating and managing the documents required by Health Authorities and part of the RIM Smart Regulatory Suite. Please contact us to discover more about how we can help you support new drug applications and submissions worldwide.

iqvia.com/eReg