

IQVIA Regulatory Templates

Drive engagement with a focus on content rather than formatting

Get a quick start on regulatory authoring

Global regulatory submissions can contain hundreds of different kinds of documents, each with strictly pre-defined requirements. Enable professional teams to focus on content, rather than formatting, with templates that additionally integrate into IQVIA SmartSolve RIM.

Save time with automated document formatting that's simple, fast, accurate

IQVIA Regulatory Templates (IRT) provide authors with a version of Microsoft® Office Word toolbars customized for regulatory applications and an intuitive, menu-driven system of agency-specified shell documents. They guide regulatory professionals quickly and easily through the selection of the right shell document for the work needed to accomplish, right down to the specific region, module and document type required.

IRT enables regulatory authoring without intensive training or time-consuming formatting struggles.



A set of over 320 agency-defined shell documents for submissions to U.S. FDA, Health Canada, EU's EMA and Swissmedic put the right formats at your fingertips for marketing and clinical trial application processes.

IRT's add-in for Microsoft Word

- Combines onto a single tab the most frequently-used Word ribbon toolbar features with specific tools for regulatory document authoring
- Bullet-proofs common header and footer placement, landscape pages, and table and figure captions

INSTANT TEMPLATES	320+ shell documents defined by regulatory agencies and ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use)
GEOGRAPHIC COVERAGE	Global regulatory templates for USA, Canada, European Union, Switzerland
CUSTOMIZED TOOLBARS	Most frequently-used Microsoft Office Word toolbar features combined with specific regulatory document management features on a single tab
FAIL-SAFE MODULES	Built-in, common header and footer placement, table and figure captions, landscape-orientation pages

Document selection

- New document function guides you through selection of correct submission-required shells
- Enter metadata prior to document creation; previously entered values are captured and can be selected from drop-down lists

Configuration

- Select from document Profiles, defining page layout and controlling what appears in headers and footers
- Four default profiles, Arial and Times New Roman fonts, Letter or A4 paper sizes
- Can define additional profiles to set company-standard margins and header/footer content
- Customized shells can be saved back to the system

Focused toolbar and other features

- IQVIA tab on Microsoft Word ribbon provides commonly-used, customized features for regulatory document creation
- Quick document outlining with numbered and unnumbered heading styles and multi-level lists
- Create tables, captions, source references and figures with a single click
- Easily apply table headings, body and notes styles
- Demystify MS Word “Section Breaks”
- Get clean Page Breaks
- Simplify authoring with 100+ symbols grouped by category

Ask about other IQVIA regulatory productivity tools

REGULATORY PDF TOOLS	ESUBMISSION VALIDATOR
Need-based wizards	Verify tech compliance ahead of submission
Fast, easy preparation, publishing, delivery	Minimize refusal to file or rejection risk
Smart, intuitive user interface	Ensure compliance with regional and ICH requirements

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. [SmartSolve® eQMS](#) centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while [SmartSolve® RIM](#) manages regulatory submissions, product registrations, and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.



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