FACT SHEET

# IQVIA Regulatory Templates

*Focus on content instead of formatting*

## Get a quick start on regulatory authoring

A regulatory submission can contain hundreds of different kinds of documents, each with strictly pre-defined requirements. Wouldn't you rather spend your valuable time creating content versus painstakingly formatting?

### SAVE TIME WITH AUTOMATED DOCUMENT FORMATTING — SIMPLE, FAST, ACCURAT

**IQVIA Regulatory Templates (IRT)** 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 you quickly and easily through the selection of the right shell document for the work you need to accomplish, right down to the specific region, module and document type required for your task.

IRT sets you up for regulatory authoring with no need for 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.

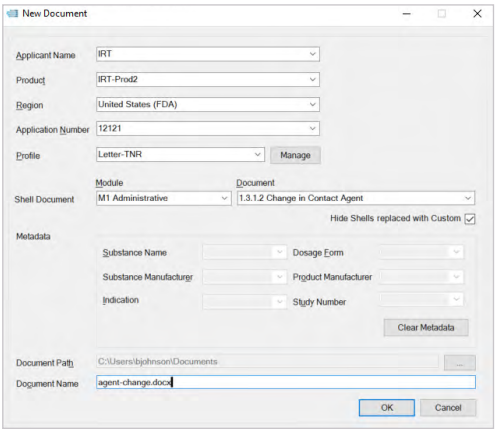
**IRT's add-in for Microsoft Word**

- 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** | 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 |

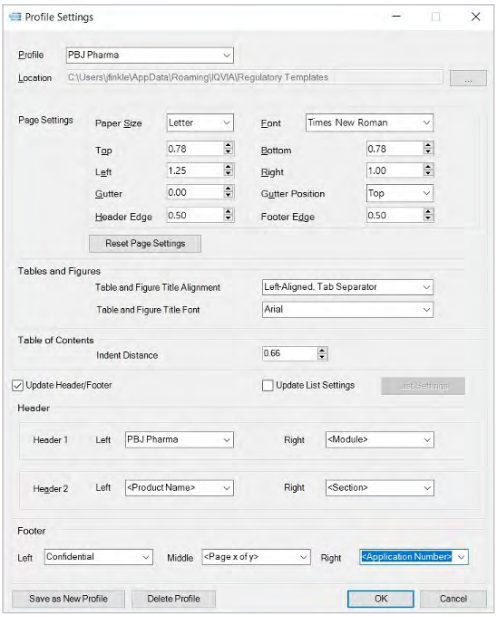
## DOCUMENT SELECTION

- 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

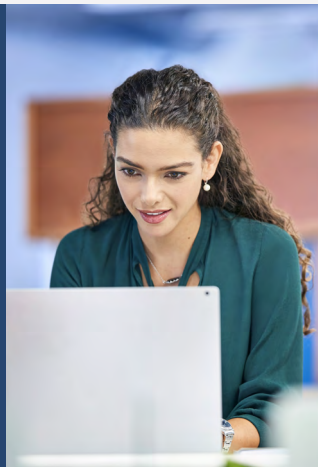
## ASK ABOUT OTHER IQVIA REGULATORY PRODUCTIVITY TOOLS

| 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 |

## TRY BEFORE YOU BUY

Test drive IRT before making a commitment. Access IQVIA Productivity Tools in a complimentary trial. Discover how they can simplify your regulatory staff’s daily activities, improving cycle times and minimizing risk.

TRY NOW



IQVIA TECHNOLOGIES

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