FACT SHEET



IQVIA eSubmission Validator

Verify your technical compliance ahead of submission

Better manage submission risk

When it's time to dispatch your documents to a regulatory agency, it's time to validate. Some companies may even validate using two different tools. Why risk losing precious time and money over technical issues? Always validate before submitting.

IMMEDIATELY ENSURE TECHNICAL COMPLIANCE

IQVIA eSubmission Validator is a multi-region application that assures technical compliance with regulatory agency requirements around the world

- Allows users to quickly and easily validate their regulatory submissions prior to actual dispatch
- Significantly minimizes risk of refusal to file or rejection due to technical issues
- Based on specifications and validation criteria published by regional authorities and ICH



- Designed to validate electronic Common Technical Document (eCTD) and Non-eCTD electronic Submissions (NeeS) standards-based documents
- Comprehensive report clearly shows users valid and invalid results including details as specified by the regional agencies
- Available as stand-alone or server-based application
- Now supports CTD 4.0 validation criteria

SUBMISSION RISK MANAGEMENT	Verify that your submission meets regulatory agency technical requirements prior to dispatch avoiding refusal to file or rejection
IMMEDIATE FEEDBACK	Receive complete report detailing status and any issues that require correction; up to 2 times faster than other available validation tools
EASE OF USE	Simple, intuitive user interface that doesn't require extensive training

GET THE DETAILS

- Uses standard settings based on each country or region along with the DTD version of the submission
- · Has the flexibility to let users validate selected module(s) and/or specific required set(s) of criteria (e.g. criteria related to PDF files only)
- Verifies and reports findings; does not modify submission content in any way
- Designed to deliver high performance and highly accurate reports

PERFORMANCE

- · Completes validation process up to 2 times faster than any other validation tool on the market
- · Works with all sizes of submissions
- · Special focus given to very large submissions to ensure fast and accurate validation

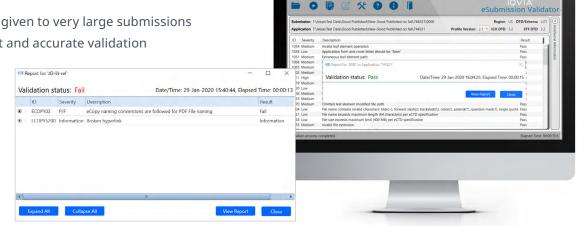
VALIDATION REPORTS

Reports generate well-organized Microsoft® Excel workbooks providing:

- Validation details
- Error details (if any)
- Submission statistics

GEOGRAPHIC COVERAGE

Available for: U.S., Canada, 28 EU EMA countries, Australia, Switzerland, Japan, Gulf Cooperation Council (Saudi Arabia, Kuwait, United Arab Emirates, Qatar, Bahrain, Oman), Jordan, South Africa, Thailand, China, South Korea



O

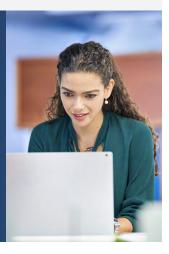
ASK ABOUT OTHER IQVIA REGULATORY PRODUCTIVITY TOOLS

REGULATORY	REGULATORY
TEMPLATES	PDF TOOLS
320+ authority-defined shell documents	Need-based wizards
Menu-driven template	Fast, easy preparation,
selection	publishing, delivery
Fit-for-purpose regulatory-specific toolbar	Smart, intuitive user interface

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



CONTACT US 2400 Ellis Road | Durham | NC 27703 | United States RegulatoryTechnology@iqvia.com iqvia.com/contactus

