Regulatory Electronic Submission Publishing

Intertek Assuris offers comprehensive end-to-end Regulatory Electronic Submission Publishing services – specializing in eCTD publishing – for the pharmaceutical and healthcare industry. Our team ensures that every submission is technically accurate, fully compliant, and delivered on time, helping clients navigate complex regulatory landscapes with confidence.

Electronic submissions are required for many regulatory submission types for regulatory authorities globally.

Why Intertek?

Leveraging industry-leading eCTD publishing tools and supporting multiple regions (e.g., United States, Canada, Europe), our team of qualified, experienced professionals consistently produce compliant, high quality, "first-time-right" submissions ranging from small to large and complex applications.

Intertek's broad capabilities

Supported by a skilled and accomplished Regulatory Affairs team, our Electronic Submission Publishing group offers full management and publishing of the following submissions in eCTD format:

- US FDA: NDA, BLA, IND, Amendments, Veterinary Submissions, DMF, Annual Report, AdPromo, all supporting submissions, etc.
- Health Canada: NDS, SNDS, ANDS, NC, CTA, DIN, DMF, all supporting submissions, etc.
- MAA, Variations, ASMF, CTA, etc.
- Conversion of paper dossiers (e.g., DMF) to eCTD format or other electronic formats.

Specific services available

- Complete end-to-end submission publishing and lifecycle management.
- Strategic, process, and technical advice.
- Document-level publishing (conversion, enhancement, optimization, OCR, bookmarking, hyperlinking, document properties, quality review).
- Submission-level publishing (eCTD compilation, naming best practices, inter-document hyperlinking, quality review, validation).
- Publishing of fully compliant ICH E3 Clinical Study Reports.
- Gateway submittal services including US FDA Electronic Submissions Gateway, Health Canada Common Electronic Submissions Gateway, EMA eSubmission Gateway, HMA Common European Submission Portal.
- Quality control review of client-generated submissions for ICH and regional compliance.
- Validation troubleshooting.
- Dataset preparation for eCTD submission (SDTM, ADaM, SEND), including creation of Simplified TS.xpt files when required.
- SPL and XML PM labelling support.
- Health Canada Regulatory Enrolment Process (REP) support.

The Intertek advantage

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Total Quality. Assured.

For more information:

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