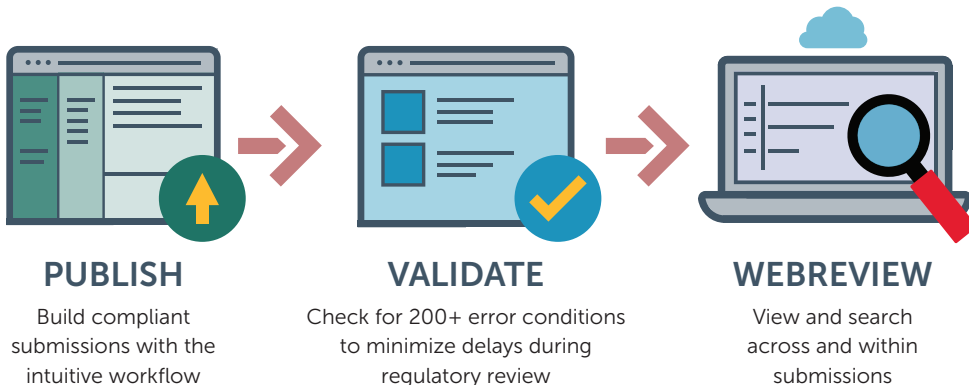


GlobalSubmit™ eCTD Platform

Simple. Efficient. Transparent.

GlobalSubmit is a full-service electronic common technical document (eCTD) platform that enables you to efficiently publish, validate and review eCTD regulatory submissions.

Choose one product to meet your needs or all three products for end-to-end submission support.



Used in **1.3M+** US FDA regulatory submissions

SIMPLIFY COMPLEX REGULATORY PROCESSES

Your regulatory affairs and operations teams benefit from the following features:

Cloud-based hosting (multi-tenant/AWS or private cloud):

- Provides access from anywhere in the world
- Enables real-time communication between global team members
- Ensures the latest enhancements and regulatory changes are available through automated updates
- Reduces the on-site IT burden and costs for routine software updates

Functionality purpose-built to enhance productivity:

- Processes only deltas or changes to PUBLISH multi-gigabyte submissions in minutes
- Loads incrementally and only reprocesses changed files to VALIDATE the files and create hyperlinks in minutes
- Dynamically opens applications and large documents for faster REVIEW

Up-to-date criteria for US FDA, European Medicines Agency (EMA), Health Canada, Nees, Swissmedic and numerous other regulatory agencies

“
The system is compliant with global standards and easy to use. The technical staff ensured that I was set up properly and could start making submissions.
”
– President, regulatory consulting company



PUBLISH

Quickly create and export submissions that meet regulatory authority requirements.

- Use the simple workflow that leads you through the steps to create compliant submissions
- Be notified of and correct validation errors in real time
- Automate creation of hyperlinks and bookmarks with LINK and QC them with CROSSCHECK
- Process document updates in bulk at industry-leading speeds



The innovative 2-step PUBLISH process

Eliminate **≥4** publishing tasks per document with LINK

Achieve **300%** increase in productivity with CROSSCHECK



VALIDATE

Gain confidence that your regulatory filings meet health authority requirements – every time.

- Assess the technical validity of your electronic regulatory submissions
- Validate a variety of submission types, including 510k
- Ensure your clinical or marketing application is not delayed by a technical rejection
- Validate submissions according to applicable regional rules

Utilize **200+** error conditions including **40+** PDF checks

Industry's most **comprehensive** error detection



WEBREVIEW

Avoid delays by improving communication with regulatory agencies based on a common view of your submissions.

- Review documents on any operating system and in any browser
- Navigate and search through applications in seconds
- Provide access to multiple reviewers
- View your application's cumulative, sequence, current and regulatory activities
- Search across and within submission applications, leafs and documents
- Work in a 21 CFR Part 11 compliant system

“
I always had great, kind, friendly and on-time support from our account manager as well as the technical support team.”

– Head of quality assurance, top 10 global pharmaceutical company

Takes **seconds**, not minutes, to find what you're looking for

Reduce data load time by **50%+**