CERTARA

AKT Health

GlobalSubmit™ eCTD Platform

Simple. Efficient. Transparent.

Certara's GlobalSubmit eCTD submissions management software simplifies your regulatory processes of publishing, validating, and reviewing your electronic common technical document (eCTD) submissions.

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

PUBLISH

Build compliant submissions with the intuitive workflow

VALIDATE

Check for 200+ error conditions to minimize delays during regulatory review

WEBREVIEW

View and search across and within submissions

Used in **1.5M+** 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

Easy-to-use interface to:

- Publish regulatory compliant PDF submissions for various Health Authorities
- Assess the technical validity of your regulatory submissions and eliminate the risk of technical rejection
- Facilitate the timely review of your eCTD submissions across various stakeholders prior to submission

Up-to-date criteria for US FDA, European Medicines Agency (EMA), Health Canada, NeeS, Swissmedic, Australia, Japan, and other regulatory agencies.

> *"For a small team that has limited time to compile and double check a submission, GlobalSubmit is a really good platform because it is all integrated, including CROSSCHECK and VALIDATE. So, you know when you generate the submission that it is compliant, and you don't need another tool for validation."*
>
> *– Jessica Pung, MS, RAC, Associate Director of Regulatory Operations, Prelude Therapeutics*

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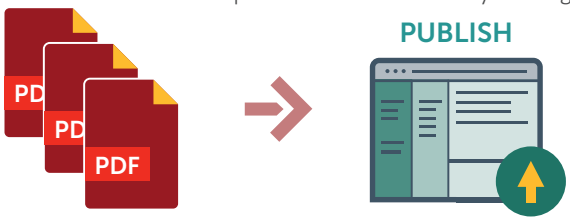
PUBLISH

Quickly create and export submissions that meet regulatory authority requirements.

- Use the simple workflow that leads you through the steps to create compliant submissions
- Identify and correct errors in real-time, and then publish on the changes with Live Validation
- 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

Independent tests show CROSSCHECK is **8x faster and 3x more accurate** when compared to traditional, manual methods of hyperlink and bookmark QC

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

"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

Takes **seconds**, not minutes, to find the information you need

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