CERTARA

Fact sheet

Regulatory Operations and Submission Leadership

Transform your regulatory submission journey

Certara Regulatory Operations and Submission Leadership Services deliver fast, efficient solutions across the entire submission lifecycle. Our proven approach combines deep expertise, advanced eCTD technology, and flexibility to support successful global submissions—all molecule types and therapeutic indications, including rare diseases and gene therapies—helping you accelerate timelines and reduce risk.

Key Benefits

Proactive Timeline Management

Anticipate regulatory challenges and stay ahead with expert project management strategies.

Quick Adaptation to Changes

Our deep regulatory knowledge enables rapid responses to new mandates and shifting requirements.

Proven Expertise in Specialized Areas

Leverage our extensive experience in managing complex submissions for innovative therapies.

Regulatory support for every stage

From investigational to marketing applications, our regulatory services cover every stage of your product's lifecycle, including:

- Investigational and marketing application submissions
- Lifecycle maintenance submissions
- Master file submissions
- Dossier management
- U.S. agent services
- Electronic transmission
- Comprehensive regulatory affairs support

> "Working with Certara was the next best thing to having a fully staffed and seasoned Regulatory Operations team on-site."
>
> Vice President, Regulatory Affairs,
> Gritstone Oncology

By choosing Certara, you gain a partner committed to accelerating your submission success with innovative solutions tailored to your unique challenges.

CERTARA

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GlobalSubmit™

Fact sheet

eCTD Software to Submit with Confidence

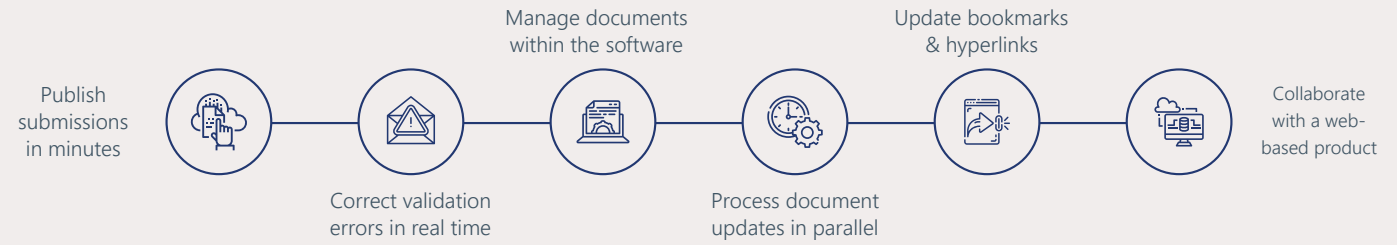
Certara GlobalSubmit eCTD Software streamlines regulatory submissions with advanced tools to publish, validate, and review effortlessly. Designed for efficiency and compliance, this 21 CFR Part 11-compliant solution accelerates timelines, reduces risks, and keeps you ahead of global regulatory standards with ease.

GlobalSubmit™ PUBLISH

PUBLISH is a desktop software that enables you to create submissions that align with a health authority's required structure, XML, and validation report.

Eliminate
≥4
publishing tasks per document

Hyperlink and bookmark QC
8x
faster compared with manual methods

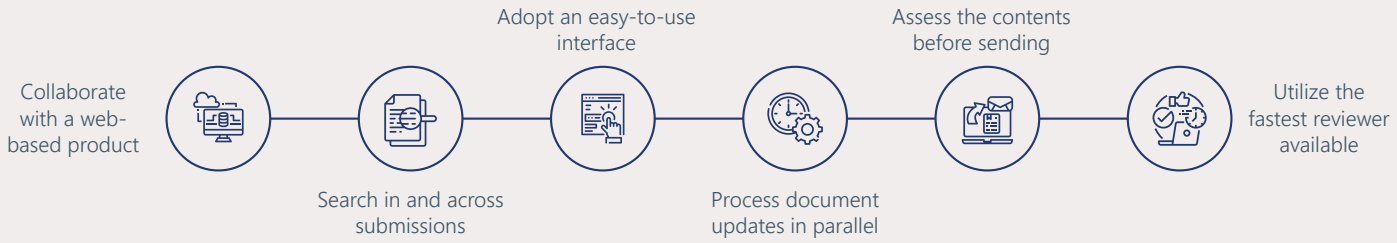


GlobalSubmit™ REVIEW

REVIEW is a web-based software that powers timely reviews of eCTD submissions across stakeholders prior to submitting to a regulatory health authority.

Utilize
200+
error conditions including 40+ PDF checks

Load Submissions
50%+
faster reducing wait time



Simplify your regulatory process with GlobalSubmit
Learn more and request a demo **certara.com/globalsubmit**

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions and regulatory agencies across 70 countries.
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