CERTARA

Document Quality and Management
Your Partner in Excellence

Why document quality matters

The integrity of any clinical development program hinges on the quality of its documentation. Regulatory submissions require consistency, accuracy, and compliance to ensure success. Certara provides expert document quality services that address these challenges, streamlining your processes and delivering outstanding results.

Tailored expertise, trusted partnership

Certara's Document Quality team delivers solutions customized to your needs with our highly trained global team and personalized approach. You'll work with a dedicated Document Quality Lead who understands your unique preferences, building a partnership you can rely on.

Comprehensive services

Document quality leadership
Seamless coordination of activities and timelines, process improvements, and document management within client or Certara systems.

Quality control
Spot-on execution with full or targeted support, ensuring external data verification, internal consistency, visual enhancements, and comprehensive checks for formatting, spelling, and abbreviations.

Document-level publishing
Effortless compliance with technical requirements, PDF conversion, navigational enhancements, and Optical Character Recognition (OCR) processing.

Document-level formatting
Streamlined text and table formatting, navigation, and template style application.

Style guide and template support
Custom creation, updates, and maintenance of style guides and lexicons with technical expertise in template applications.

Expert QC for regulatory success
Thousands of expertly quality-controlled clinical, nonclinical, and CMC (chemistry, manufacturing, and controls) documents have supported successful regulatory submissions.

Around-the-clock global support
Our global team ensures seamless transitions between document finalization and publication, ensuring efficiency and quality at every stage of the drug development process.

Save time and focus on content with Certara's eCTD Template Suite

- Over 280 customizable templates
- A specialized toolbar with standardized shortcuts and symbols
- Annual updates to reflect regulatory changes
- Onboarding, training, and full technical support included

Achieve consistency, streamline your review process, and reduce formatting time.

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Why Certara?

Experience

More than 90% of all novel drugs approved by the U.S. FDA since 2014 were supported by Certara services or technology

Quality

100% of 230+ regulatory submissions over the past five years were delivered on or ahead of schedule

Tech-enabled

Expert use of technology solutions to accelerate timelines and increase the quality of outputs across our regulatory writing, editing, and publishing offerings, including CoAuthor™, GlobalSubmit™, PerfectIt, ISI Toolbox, and more.

CoAuthor™

Certara's CoAuthor™ provides transparency, consistency, and collaboration to allow medical writing teams to accelerate the drafting and submission of quality and compliant regulatory documents.

GlobalSubmit™ eCTD Software

With Certara's GlobalSubmit™ eCTD submissions management software, you'll provide your regulatory team the tools they need to efficiently publish, validate, and review your eCTD submissions.

Flexible quality solutions

Whether your team has known needs in advance or has a last-minute unexpected need, the Certara team is ready to help. Certara QC, formatting, and document-level publishing offerings can be leveraged with little notice.

Document quality leaders

Laura Velarides
Associate Director/Service Line Head, Document Quality

Sarah Steffin
Regulatory Services Manager, Document Quality

See how using style guides and lexicons streamline submissions

Watch the webinar to discover proven strategies for mastering style guides and lexicons

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,600 biopharmaceutical companies, academic institutions and regulatory agencies across 70 countries. Visit **certara.com** | Copyright ©2025 Certara. All rights reserved.

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