CERTARA

Fact sheet

AI-Enabled Regulatory Writing

Regulatory writing and medical communication are entering a new era. Prepare yourself with the right team and technology.

Biomedical intelligence is exploding. Studies are growing more complex and the rules for regulatory documents are changing constantly. Facing these challenges, how can today's regulatory and medical writers produce the reports, narratives, and related deliverables expected of them in less time, with greater technical accuracy?

Partnering with the right team is essential. So is using the right technology—a platform powerful enough to keep pace with the information revolution. The Certara solution provides both, delivering speed, reproducibility, and scientific quality, at scale.

Why partner with Certara's regulatory writers?

Experience

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

Trust

Our regulatory team reached its 300th regulatory submission in 2023.

Technology

Certara's CoAuthor™ , a generative AI-enabled regulatory writing platform provides transparency, consistency, and collaboration to allow regulatory writing teams to accelerate the drafting and submission of quality and compliant regulatory documents

Expertise across therapeutic areas and document types

Certara is home to more than 400 MD, PharmD & PhD Drug Development Scientists, Regulatory Writers, and several Centers of Excellence, including Rare Disease and Pediatrics, making our team your best choice for success. Together, they offer a range of tailored medical and regulatory writing capabilities that cover the full drug development continuum.

- CMC and Nonclinical Writing
- Safety and Annual Reports
- Clinical Submission Writing
- Biostatistics and Programming
- Study-Level Documentation
- Document Publishing

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CoAuthor

The Generative AI-Enabled Regulatory Writing Platform

Feature	CoAuthor	Microsoft Copilot	Other Regulatory Writing Tools
Regulatory Document Template Suite	X		
Structured Content Authoring	X		X
Regulatory-specific Generative AI	X		X
Auto Styling & Hyperlinking	X		
Traceability & Version Control	X		X
Real Time Preview	X	X	
Collaborative Authoring & Review	X		X
Meta-Data & Document Repository	X		
Automated De-identification	X		
MS Word Integration	X	X	
Tech-enabled Regulatory Writing Services	X		

Today's regulatory writing technology needs to get smarter, while remaining user-friendly and collaborative. CoAuthor expedites the writing process by bringing three capabilities into one familiar user interface: fast template selection, structured content authoring, and generative AI.

eCTD Template Suite

Spend 50% less time formatting your document by applying your style guides to more than 275 eCTD compliant templates.

Structured Content Authoring

Reuse any portion of your writing, from a compound name to complete paragraphs on mechanism of action, across all your documents. Collaborate with your peers on a single source of truth and explanatory style.

Generative AI

Leverage a life science specialized GPT behind your firewall for secure, prompt-based text generation. CoAuthor features a proprietary retrieval augmented generation (RAG) based architecture which significantly reduces hallucinations and provides references to source material for simplified QC of documents.

The Power of CoAuthor Enables Regulatory Writing Teams to:

- Focus on key decision points
- Ensure consistency and quality through standardization
- Reduce time and costs through faster authoring and review

Take your regulatory writing program to the next level:
certara.com/ai-enabled-regulatory-writing/

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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