

Automated Writing Without the Compromise

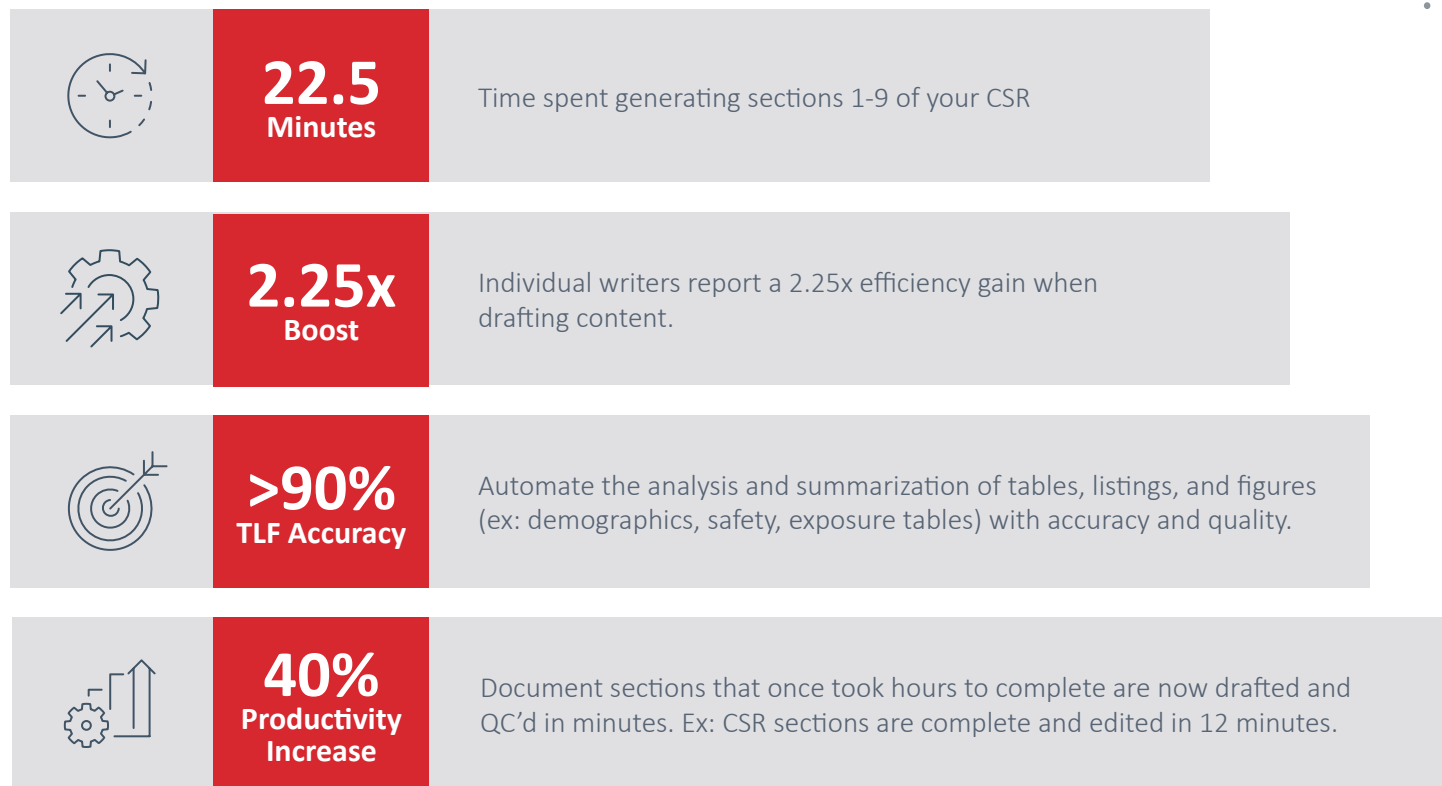
Generative AI for Regulatory Writing

CoAuthor combines the power of generative AI and structured content authoring to deliver transparency, consistency, and collaboration to allow medical writing teams to accelerate the drafting and submission of quality and compliant regulatory documents.



CoAuthor Efficiencies

When leveraging CoAuthor's suite of generative AI and structured content authoring tools, writers report¹:



Microsoft Word Integration

Regulatory writers can continue to work where they're most familiar and comfortable because CoAuthor can be leveraged directly in Microsoft Word. CoAuthor's structured content authoring and specialized GPT operate alongside your existing macros and toolbars, allowing you to further accelerate document drafting without having to develop an entirely new process. Writers also save time and headache on formatting with auto-styling to eliminate inconsistencies and build continuity throughout the documents.

CoAuthor's generative AI is organization-specific ensuring full control over system data access and processing. In addition to AI-driven automation, CoAuthor includes a suite of smart authoring tools to further accelerate the submission creation process:



Streamline formatting with a library of over 280+ global and regional eCTD compliant templates.



Establish generative AI best practices with custom prompt libraries.



Flexibly manage source files including .docx, .rtf, xpt, .xlxs, .csv, and sas7bdat.



Simplify content reuse and transcription with study attribute extraction.

QC with Ease

CoAuthor delivers transparency and control around the use of generative AI, allowing writers to quickly identify focus areas for QC:

- In document content blocks highlight sections of text that are AI generated. Content blocks are labeled to know exactly what generative AI prompt was used and where.
- Prompt referencing allows writers to quickly review AI generated content against source data.
- Auto-populated comments and track changes pinpoint what source data has been added to a draft, ensuring the latest data and source files are in use.

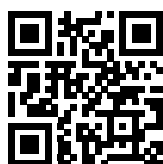
Improving Writers' Productivity and Job Satisfaction

In a blinded study, college-educated writers exposed to generative AI presented a 40% productivity increase, while improving quality of writing overall. More importantly, those same writers reported higher job satisfaction than those not leveraging AI.²

Reference

¹ Performance metrics reported from preliminary results, based on tests conducted by Certara.

² Shakked Noy, Whitney Zhang, Experimental evidence on the productivity effects of generative artificial intelligence. *Science* 381, 187-192 (2023). DOI: 10.1126/science.adh 2586



Life Science Specialized GenAI for Regulatory Writing
Learn more and request a demo
certara.com/coauthor

About Certara

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 66 countries.

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