



Certara Launches Next Generation CoAuthor™ Generative AI Regulatory Writing Software

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AI-enabled solutions accelerate regulatory and medical writing processes, enhancing quality, transparency, and efficiencies

RADNOR, Pa., June 17, 2024 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in model-informed drug development, today unveiled its next-generation [CoAuthor](#) regulatory writing software. CoAuthor is an advanced writing platform designed for medical writers. It combines generative AI, document templates, Microsoft Word integration, and structured content authoring tools. CoAuthor accelerates the creation of regulatory documents while maintaining a “human in the loop” approach to the use of generative AI.

Medical writing is a critical part of drug development. It relies on manual processes which have not changed significantly over the past two decades. Drug development pipelines increasingly comprise precision medicine therapies that depend on advanced biomedical knowledge. Today’s medical writers must translate complex study designs and data into documents that contextualize research results for different audiences. They need better ways to synthesize numerous sources of knowledge and securely connect them to their data and documents.

“Life Sciences companies are looking for secure, generative AI solutions that are specialized for drug development,” said [William Feehely](#), Ph.D., Certara CEO. “Certara has the proven technical and scientific expertise required to maximize the potential of generative AI for regulatory and medical writing.”

Built by writers, for writers, CoAuthor is easy to use and combines a life science specialized, secure, client-specific GPT with structured content authoring and comprehensive eCTD regulatory writing templates. With CoAuthor, medical writers can streamline the document drafting process, allowing more time for content curation, collaboration, and quality control. Fully integrated with Microsoft Word, CoAuthor enables writing teams to use familiar tools, systems, and processes while ensuring consistency and quality. Certara clients will have the flexibility to work with CoAuthor as part of a comprehensive regulatory writing solution, at the program level and across the enterprise.

“We’ve worked extensively with the experienced team of medical writers at Certara to build a next-generation product for medical writers that fully incorporates the value of generative AI,” said Christopher Bouton, Ph.D., Senior Vice President, Artificial Intelligence, Certara. “With CoAuthor, medical writers can create consistent, reproducible content, improving the time to first draft by at least 30%. Our human-in-the-loop model significantly reduces drafting time, while still enabling writers to use the generated content in the ways that they decide is best.”

To learn more about CoAuthor solutions for regulatory writing, join the Certara team at the DIA Annual Meeting in San Diego, CA at booth 2319. Additionally, Certara leaders Chris Bouton and Demetrius Carter, Senior Vice President, Regulatory Services, Certara, will present the new platform in an Innovation Theatre session, [Technology-Enabled Writing – Use CoAuthor™ as your Fully Integrated GenAI Medical Writing Platform](#), on June 17th. More information about Certara’s presence at the DIA Annual Meeting is available [here](#).

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. Learn more at [certara.com](#).

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