Regulatory Writer

Job ID
REQ-10049339
Απρ 20, 2025
China

Περίληψη

We are seeking a Regulatory Writer to author clinical documents, plan the responsible parts in CSRs, ensuring medical writing resources are adequate in assigned programs and contribute in clinical submissiont team.

About the Role

Key Responsibilities:

- To author, review and manage high quality clinical and safety documents: complex Clinical Study Reports (CSR), Development Safety Update Reports (DSUR), Risk Management Plans (RMP), submission documents (e.g., summaries of clinical efficacy and safety, summaries of clinical pharmacology and biopharmaceutics).
- Core member of Clinical Trial Team (CTT) / contributor to Safety Management Team.
- Major contributor to planning of data analyses and presentation used in CSRs and submission documents.
- Documentation specialist in CTTs and CSTs to ensure compliance of documentation to internal company standards and external regulatory guidelines. Provide content expertise and guidance for clinical portions of the CTD.
- Program Writer ensuring adequate medical writing resources are available for assigned program and consistency between documents. Extended member of International Clinical Team (ICT)
- Lead Writer for simple submissions, contributing to key messaging and pooling strategy, providing content guidance, and ensuring compliance of documentation to internal company standards and external regulatory guidelines. Core member of Clinical Submission Team (CST).
- Contribute to process improvement in DE and/or cross-functional initiatives or activities. Coach and/or mentor less experienced writers.
- Leader in cross-functional communication to optimize feedback and input towards high quality documents. Maintain audit, SOP and training compliance.

Essential Requirements:

- Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable. Fluent English (oral and written).
- Advanced knowledge of and experience in global regulatory environment and process (key regulatory bodies, key documents, approval processes, safety reporting requirements).Advanced knowledge of and repeat experience in global registration of drugs (complex submissions).
- Excellent communication skills (written, verbal, presentations). Advanced knowledge of biostatistics principles. Strong ability to prioritize and manage multiple demands and projects. Ability to define and solve complex problems (“Problem-solver”)

Desirable Requirements:

- ≥ 3 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus in-depth knowledge of medical writing processes.
- Some experience in managing global, cross-functional teams or simple global projects.
- Broad knowledge and future oriented perspective. Proven track record in matrix environment

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Job Type
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Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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