Regulatory Writer

Job ID
REQ-10066157

11月 04, 2025

China

摘要

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

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部门
Development

Business Unit
Innovative Medicines

地点
China

站点
Shanghai (Shanghai)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

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