Senior Medical Writer 1

Job ID
REQ-10037230

1月 26, 2025

India

摘要

To write, review and manage the preparation of high quality clinical documents for CPO ' s and global organization. Provide authoritative documentation related consultancy to other line functions.

About the Role

Senior Medical Writer I

Location - Hyderabad #LI Hybrid

About the Role:

To write, review and manage the preparation of high quality clinical documents for CPO ' s and global organization. Provide authoritative documentation related consultancy to other line functions.

Key Responsibilities:

- To author, review and independently manage high quality clinical documents: Clinical Study Reports (CSR) including narratives, Protocol, Informed Consent Form (ICF).
- To write CTD modules and other safety documents (DSURs, RMPs) independently
- Liaise with medical/clinical experts, statisticians, investigators in concept development when protocol is being developed and work in a collaborative fashion for global/CPOs
- Contribute to planning of data analyses and presentation to be used in CSRs
- Ensure compliance of documentation to internal company standards and external regulatory guidelines.
- Supervise outsourcing to external medical writers, if required.
- Training and mentoring of associates as required.
- Contribute to cross-functional communication to optimize feedback and input towards high quality documents. Maintain audit, SOP and training compliance.

Commitment to Diversity & Inclusion: :

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

Essential Requirements:

- Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/medicine/pharmacy is desirable.
- 3 years of regulatory medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus in-depth knowledge of medical writing processes.
- Good communication skills (written, verbal, presentations)
- Good operational knowledge of clinical trial reporting.
- Good knowledge of biostatistics principles.
- Strong ability to prioritize and manage multiple demands and projects.
- Knowledge of and experience in global regulatory environment and processes (key regulatory bodies, key documents, approval processes, safety reporting requirements).
- Good experience in managing global, cross-functional teams or simple global projects.

Desirable Requirements:

- Demonstrated ability to establish effective working relationship in a matrix and multicultural environment.
- Demonstrated presentation and diplomacy skills.
- Strong customer-oriented mindset.

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part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Commitment to Diversity and Inclusion:
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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Operations

Business Unit
Innovative Medicines

地点

India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

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.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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