NOVARTIS

Senior Medical Writer 1

Job ID
REQ-10037230
Jan 26, 2025
India

Summary

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.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:
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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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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

Division
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Business Unit
Innovative Medicines
Location
India
Site

Hyderabad (Office)
Company / Legal Entity
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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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