Senior Regulatory Writer

Job ID
REQ-10012472
Ago 11, 2024
India

Sommario

That is the approximate number of individual regulatory documents the dynamic team at Regulatory Writing and Submissions (RWS) planned, developed and wrote. And that’s just in 2019! Come, join a global team of nearly 200 regulatory professionals- life scientists, clinicians and project managers across 6 countries and support Novartis in its mission to bring innovative medicines to patients worldwide. You will collaborate with colleagues from Statistics, Data Management and Clinical Development and have the opportunity to analyze data and derive key messaging to secure approvals from Health Authorities. Read on for details about the role and how you can join a world-class organization at the forefront of the industry to advance your career.

About the Role

Position Title : Senior Regulatory Writer

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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.

• Core member of Clinical Trial Team (CTT) / contributor to Safety Management Team. Documentation specialist in CTTs and Clinical Submission Teams (CST) to ensure compliance of documentation to internal company standards and external regulatory guidelines.

• Program Writer ensuring adequate medical writing resources are available for assigned program and consistency between documents.

• 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.

• Contribute to process improvement in RWS 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.

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.

Role Requirements :
Essential Requirements:

• ≥ 4 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus in-depth knowledge of medical writing processes.

• Advanced knowledge of and experience in global regulatory environment and process.

• 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”)

• Broad knowledge and future oriented perspective. Ability to drive and manage organizational and team performance across cultures.

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

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

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Innovative Medicines
Posizione
India
Sito
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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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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