Expert Regulatory Writer

Job ID
REQ-10056707

7月 04, 2025

India

摘要

To write, review and manage the production of high quality clinical and safety documentation for submission to regulatory authorities in support of marketing applications. To provide authoritative documentation-related consultancy to other line functions. To coach, mentor and train less experienced writers.

About the Role

Major accountabilities:

- To author, review and/or independently manage high quality clinical and safety documents: complex Clinical Study Reports (CSR), Risk Management Plans (RMP), complex CTD submission documents (clinical overviews, summaries of clinical efficacy and safety, summaries of clinical pharmacology and biopharmaceutics), other documents for health authorities (e.g., Briefing Books, answers to questions).

- Lead writing team for complex submissions, actively contributing to key messaging and pooling strategy, providing expert content guidance for clinical portions of the CTD, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
- Input into planning of data analyses and presentation (statistical analysis plan review and meetings) used in CSRs, submission documents and/or answers to questions.
- Documentation expert in GCTs and CSTs to ensure compliance to internal company standards and external regulatory guidelines.
- Provide content and strategic expertise for clinical portions of the CTD.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Delivery of high quality clinical and safety documents in time and in compliance with internal and external standards -Customer / partner/ project feedback and satisfaction -Adherence to Novartis policy and guidelines

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Project Management.
- Collaborating across boundaries.
- Operations Management and Execution.
- Representing the organization.

Skills:

- Clinical Research.
- Clinical Trials.
- Detail Oriented.
- Medical Writing.
- People Management.
- Project Management.
- Regulatory Compliance.
- Safety.

Languages :

- English.

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

部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Office)

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

Alternative Location 1
Hyderabad (Office), India

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.

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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