Senior Regulatory Writer

Job ID
REQ-10045011
Μαρ 27, 2025
Japan

Περίληψη

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About the Role

Major Accountabilities
1. To author, review and manage high quality clinical documents and safety documents: complex Clinical Study Reports (CSR), submission documents [clinical portions of the Common Technical Document (CTD)], other documents for health authorities [e.g., Briefing Books (BB), answers to questions, PMS and re-examination related documents].
2. Extended member of Japan Project Team (JPT) and Integrated Clinical Trial Team (iCTT). Core member of Japan Submission Team (JST).
3. Major contributor to planning of data analyses and presentation used in CSRs and submission documents.
4. Documentation specialist in iCTTs and JSTs to ensure compliance of documentation to internal company standards and external regulatory guidelines. Provide content expertise and guidance for clinical portions of the CTD.
5. Lead Writer for submissions, contributing to key messaging and pooling strategy, providing content guidance, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
6. Contribute to process improvement in RWS and/or cross-functional initiatives or activities.
7. Coach and/or mentor less experienced writers.
8. Leader in cross-functional communication to optimize feedback and input towards high quality documents.
9. Maintain audit, SOP and training compliance.
10. Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
11. 100% timely delivery of all training requirements including compliance.

Education:(minimum/desirable)

Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.

Languages:

Fluent Japanese/English (oral and written).

Experience / Professional Requirement:

- ≥ 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 global regulatory environment and process (key regulatory bodies, key documents, approval processes).
- Advanced knowledge and experience, and demonstrated record of accomplishment in Japan local registering of drugs.
- 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.
- Proven track record in matrix environment.
- Some experience in managing global, cross-functional teams or simple global projects.
- Ability to motivate and coach people.

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

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

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.china@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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Business Unit
Universal Hierarchy Node
Τοποθεσία
Japan
Τοποθεσία
Toranomon (NPKK Head Office)
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

midcareer-r.japan@novartis.com

Job ID
REQ-10045011

Senior Regulatory Writer

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