Senior Regulatory Writer

Job ID REQ-10045011 Mar 27, 2025 Japan

Summary

~

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 reexamination 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.

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. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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 Development **Business Unit** Universal Hierarchy Node Location Japan Site 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 midcareerr.japan@novartis.com Job ID REQ-10045011 **Senior Regulatory Writer**

Apply to Job

Source URL: https://prod1.novartis.com/careers/career-search/job/details/req-10045011-senior-regulatory-writer-ja-jp

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture

- 2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
- 3. mailto:diversityandincl.china@novartis.com
- 4. https://talentnetwork.novartis.com/network
- 5. https://www.novartis.com/about/strategy/people-and-culture
- 6. https://talentnetwork.novartis.com/network
- 7. https://www.novartis.com/careers/benefits-rewards
- 8. https://novartis.wd3.myworkdayjobs.com/ja-JP/Novartis_Careers/job/Toranomon-NPKK-Head-Office/Senior-Regulatory-Writer_REQ-10045011-3
- 9. mailto:midcareer-r.japan@novartis.com
- 10. https://novartis.wd3.myworkdayjobs.com/ja-JP/Novartis_Careers/job/Toranomon-NPKK-Head-Office/Senior-Regulatory-Writer_REQ-10045011-3