Senior Regulatory Writer

Job ID
REQ-10050255

10月 20, 2025

USA

摘要

Title: Senior Regulatory Writer, Remote

“This position can be based remotely anywhere in the U.S. Please note that this role would not provide
relocation as a result. The expectation of working hours and travel will be defined by the Hiring Manager. This position will require minimal travel”

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

#LI-Remote

Key Responsibilities:

1. 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 (e.g., summaries of clinical efficacy and safety, summaries of clinical pharmacology and biopharmaceutics).
2. Core member of Clinical Trial Team (CTT) / contributor to Safety Management Team.
3. Major contributor to planning of data analyses and presentation used in CSRs and submission documents.
4. Documentation specialist in CTTs and Clinical Submission Teams (CST) 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. Program Writer ensuring adequate medical writing resources are available for assigned program and consistency between documents. Extended member of International Clinical Team (ICT)
6. 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. Core member of CST.
7. Contribute to process improvement in RWS and/or cross-functional initiatives or activities.
8. Coach and/or mentor less experienced writers.
9. Leader in cross-functional communication to optimize feedback and input towards high quality documents.
10. Maintain audit, SOP and training compliance.

About the Role

Requirements:

- Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.
- $\geq$ 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 (key regulatory bodies, key documents, approval processes, safety reporting requirements).
- Advanced knowledge of and repeat experience in global registration of drugs (complex submissions).
- Excellent communication skills (written, verbal, presentations)
- Advanced knowledge of biostatistics principles.
- Strong ability to prioritize and manage multiple demands and projects.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $114,100/yr and $211,900/yr; ***however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.*** The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range

of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
Remote, US

站点
Remote Position (USA)

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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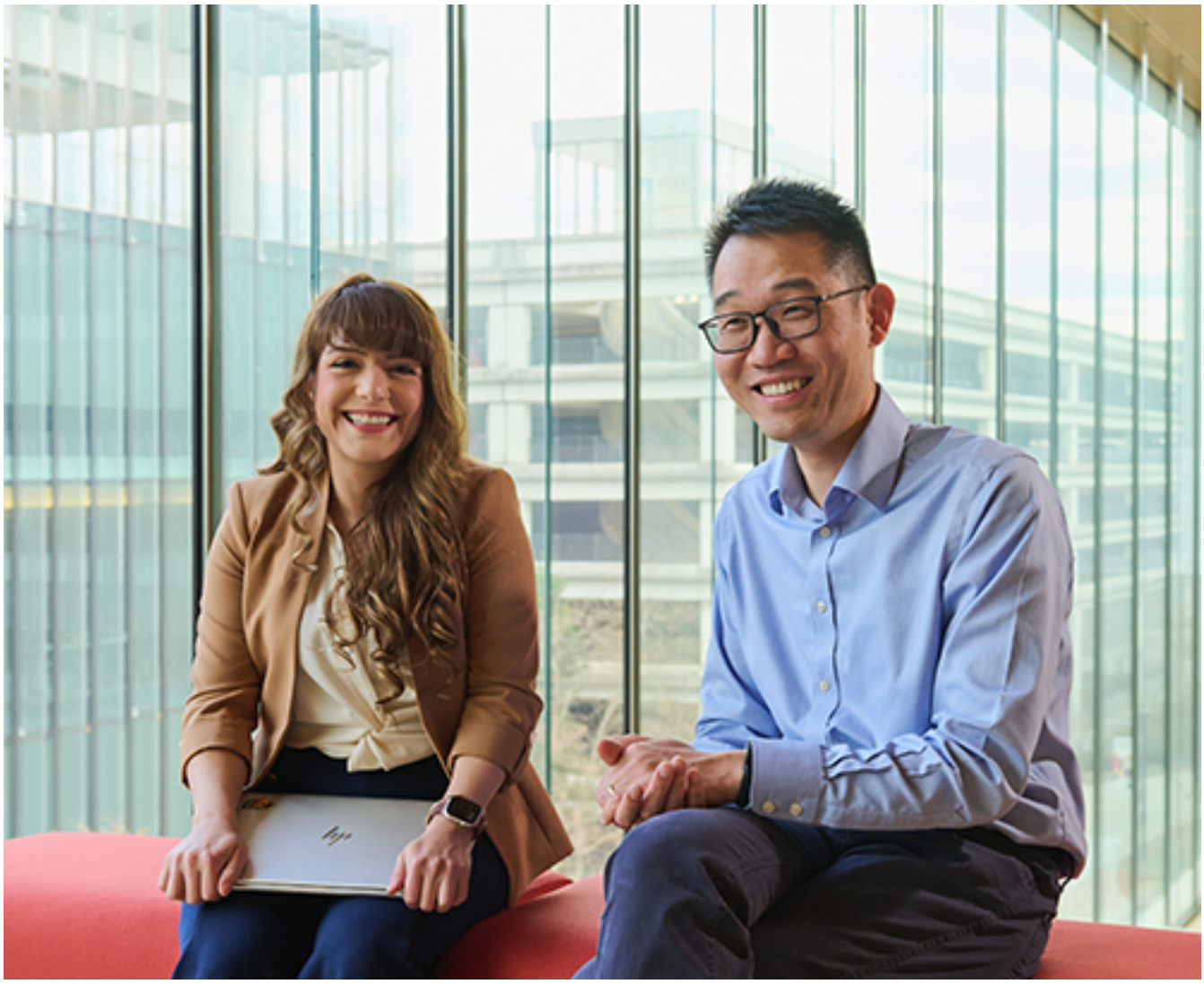

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