NOVARTIS

Senior Scientific/Regulatory Writer

Job ID
REQ-10005398
Dec 24, 2024
USA

Summary

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require minimal travel.
The Senior Regulatory Writer will be responsible for writing and reviewing high quality clinical and safety documentation for submission to regulatory authorities. Major Activities

#LI-Remote
Key Responsibilities:
1.To author and review high quality clinical and safety documents: non-registration Clinica lStudy Reports (CSR), Development Safety Update Reports (DSUR), Risk Management Plans (RMP).
2.Lead for outsourced Narrative projects. Coordinate other outsourced activities in RWS.
3.Core member of Clinical Trial Team (CTT) / participate in Safety Management Team(SMT).
4.Actively participate in planning of data analyses and presentation used in CSRs.
5.Act as documentation consultant in CTTs and SMTs to ensure compliance of documentation to internal company standards and external regulatory guidelines.
6.May act as Program Writer ensuring adequate medical writing resources are available for assigned program and consistency between documents.
7.Act as liaison between CTTs and publishing teams to ensure timely delivery of final documents for publishing.
8.Support the development of RWS through participating in RWS workstreams and other related activities.

About the Role

Essential Requirements:

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

- ≥ 2 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus strong knowledge of the medical writing processes. Preferred
- Good knowledge of and some experience in global regulatory environment and process (key regulatory bodies ,key documents, approval processes, safety reporting requirements).
- Knowledge of process for and some experience in global registering of drugs (simple submissions).
- Excellent communication skills (written, verbal, presentations)

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of

employment is expected to be between $124,000 and $186,000/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, 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 who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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.

Division
Development
Business Unit

Innovative Medicines
Location
USA
State
Remote, US
Site
Remote Position (USA)
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Alternative Location 1
East Hanover, New Jersey, USA
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Job ID
REQ-10005398

Senior Scientific/Regulatory Writer

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List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
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