NOVARTIS

Senior Regulatory Writer

Job ID
393223BR
Mar 14, 2024
USA

About the Role

This is a Remote Position

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.

The pay range for this position at commencement of employment is expected to be between $118,400 and $177,600 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.

Diversity & Inclusion / EEO

We are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran

status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Accessibility and Reasonable Accommodations: Individuals in need of a reasonable accommodation due to a medical condition or disability for any part of the application process, or to perform the essential functions of a position, please let us know the nature of your request, your contact information and the job requisition number in your message:

- Novartis: e-mail us.reasonableaccommodations@novartis.com or call +1 (877)395-2339
- Sandoz: e-mail reasonable.accommodations@sandoz.com or call: +1-609-422-4098

Role Requirements

• ≥ 4 years medical writing experience or other relevantpharma industry experience combined with scientific andregulatory knowledge, plus in-depth knowledge of medicalwriting processes. Preferred
• Advanced knowledge of and experience in global regulatoryenvironment and process (key regulatory bodies, keydocuments, approval processes, safety reportingrequirements). Preferred
• Advanced knowledge of and repeat experience in globalregistration of drugs (complex submissions).
• Excellent communication skills (written, verbal, presentations)
• Advanced knowledge of biostatistics principles.
The company provides reasonable accommodations for otherwise qualified individuals with medical restrictions if an accommodation can be provided without eliminating the essential function of driving.
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/careers/benefits-rewards

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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

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

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connected and learn about suitable career opportunities as soon as they come up:
https://talentnetwork.novartis.com/network

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Employment Type
Regular
Shift Work
No
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Senior Regulatory Writer

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