NOVARTIS

Expert Regulatory Writer

Job ID
REQ-10015462
Set 03, 2024
USA

Sommario

The Expert Regulatory Writer will be responsible for writing, reviewing and/or managing the production of high quality clinical and safety documentation for submission to regulatory authorities in support of marketing applications. To provide authoritative documentation-related consultancy to other line functions. To coach/mentor and/or train less experienced writers.

Location: The ideal location for this role is East Hanover, NJ site but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to specific NJ site for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require some travel.

About the Role

Major accountabilities:

- To author, review and/or independently manage high quality clinical and safety documents: complex Clinical Study Reports (CSR), Risk Management Plans (RMP),complex CTD submission documents (clinical overviews, summaries of clinical efficacy and safety, summaries of clinical pharmacology and biopharmaceutics), other documents for health authorities (e.g., Briefing Books, answers to questions).
- Lead writing team for complex submissions, actively contributing to key messaging and pooling strategy, providing expert content guidance for clinical portions of the CTD, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
- Ad-hoc member of Clinical Trial Team (CTT) / extended member of Safety Management Team (SMT). Core member of multiple Clinical Submission Teams (CST). Extended member of Global Clinical Teams (GCT).
- Input into planning of data analyses and presentation (statistical analysis plan review and meetings) used in CSRs, submission documents and/or answers to questions.
- Documentation expert in GCTs and CSTs to ensure compliance to internal company standards and external regulatory guidelines. Provide content and strategic expertise for clinical portions of the CTD.
- Program Writer for large and/or complex programs ensuring adequate medical writing resources are available for assigned program and consistency between documents.
- Lead process improvement in RWS and cross-functional initiatives and/or activities.
- Can identify training needs to foster high level of performance within RWS. Coach and/or mentor less experienced writers.

Minimum Requirements:

- Minimum university life science degree or equivalent is required.
- Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.
- 6 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes.
- Expert knowledge of and repeat experience in global regulatory environment and process (key regulatory bodies, key documents, approval processes, safety reporting requirements).
- Expert knowledge, extensive experience, and demonstrated record of accomplishment in global registering of drugs.
- Excellent communication skills (written, verbal, presentations)
- Expert knowledge of biostatistics principles.
- Proven ability to prioritize and manage multiple demands and projects.
- Demonstrated ability to define and solve complex problems (“Problem-solver”).

The pay range for this position at commencement of employment is expected to be between $151,200.00 and $226,800.00 per 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.

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.

Divisione
Development
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Distant Employee - Distant Working Arrangement (DWA) (USA)
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U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
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Employment Type
Regular
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REQ-10015462

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