NOVARTIS

Associate Director Regulatory Writing

Job ID
394328BR
Mar 14, 2024
Estados Unidos

About the Role

This is a remote position
To write, review and/or handle 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.
Major Activities
1. To author, review and/or independently handle high quality clinical and safety documents: Clinical Study Reports (CSR), Risk Management Plans (RMP), 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).
2. Lead writing team for complex submissions, actively contributing to key messaging and pooling strategy, providing specialist content guidance for clinical portions of the CTD, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
3. 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).
4. Input into planning of data analyses and presentation (statistical analysis plan review and meetings) used in CSRs, submission documents and/or answers to questions.
5. Documentation specialist 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.
6. Program Writer for large and/or complex programs ensuring adequate medical writing resources are available for assigned program and consistency between documents.
7. Lead process improvement in RWS and cross-functional initiatives and/or activities.

• 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. preferred
• 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.

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

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• ≥ 6 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes. preferred
• 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.

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.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $144,000-$216,000year; 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.

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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Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Research & Development
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Employment Type
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Shift Work
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Associate Director Regulatory Writing

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regulatory-writing

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