NOVARTIS

Global Program Regulatory Manager - Cardio-Renal-Metabolic

Job ID
REQ-10043944
Mar 24, 2025
USA

Summary

The Global Program Regulatory Manager (GPRM) works with some independence under limited supervision to provide strategic and operational regulatory direction and may support the RA global program team (GPT) representative and/or Global Therapeutic Area Lead (GTAL) for programs through development, registration and approval/post approval. The GPRM ensures the execution of regulatory plans in line with global regulatory strategy in close collaboration with the RA GPT representative and/or GTAL. In certain cases, the GPRM may act as the GPT representative. The GPRM is a member of the RA sub team and may indirectly report to the RA GPT representative for the project and may have responsibility for leading regional RA sub teams.

About the Role

#LI-Hybrid

Key Responsibilities

Regulatory Strategy

- Provide input to global program regulatory strategy, including regulatory designations & innovative approaches
- Coordinates regulatory readiness with other line functions, Country Organizations & Regions, representing Regulatory Affairs (RA) or leads in regional RA or cross-functional activities providing strategic input into cross functional deliverables
- Contributes to the development and maintenance of key documents, determines the requirements and coordinates the activity for Health Authority (HA) interactions

Regulatory Submissions

- Leads planning, preparation and submission of clinical trials.
- Leads implementation of the defined global registration strategy into regional submissions worldwide by country organizations
- Coordinates, plans and prepares for submission of initial registrations and post approval applications, and the preparation, review and maintenance of local product information as assigned
- Lead regulatory activities during HA reviews, responding to questions and HA interactions

Regulatory Excellence & Compliance

- Ensures timely RA input and submission of regulatory compliance and maintenance reports, maintaining

regulatory information in compliance databases and document management systems

Essential Requirements:

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred.
- Experience with regulatory submission and approval processes in 1 or more major regions.
- Experience in a global/matrix environment or cross- functional teams in the pharmaceutical industry.
- Experience in HA negotiations.
- 2-4 years involvement in regulatory and drug/biologic development spanning activities in Phases I-IV in the following areas:
  Innovation in regulatory strategy | Understanding of post-marketing/brand optimization strategies and commercial awareness preferred | Involvement in an dossier submissions and approvals | HA negotiations | Drug regulatory submission and commercialization in region | Analysis and interpretation efficacy and safety data | Regulatory operational expertise | Strong interpersonal, communication, negotiation and problem solving skills | Basic organizational awareness (e.g., interrelationship of departments, business priorities).

The pay range for this position at commencement of employment is expected to be between $114,100 and $211,900 /year; however, while salary ranges are effective from 1/1/25 through 12/31/2025, 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

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

Skills:

- Clinical Trials.
- Detail Oriented.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- Regulatory Compliance.

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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.

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