NOVARTIS

Sr Global Program Regulatory Manager (Associate Director level) Cardio-Renal-Metabolic

Job ID
REQ-10043959

May 06, 2025

USA

Summary

Directs the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Provides strategic product direction to teams on interaction and negotiates evidence with regulatory agencies. Interacts and negotiates with regulatory agency personnel in order to expedite approval of pending registration and answers any questions. Serves as a regulatory liaison on the project team throughout the product lifecycle. Ensures rapid and timely approval on of new drugs, biologics/biotechnology and/or medical devices and continued approved status of marketed drugs or medical devices. Serves as regulatory representative to marketing or research project teams and government regulatory agencies. Provides advice to development and/or marketing teams on manufacturing changes, line extensions, technical labeling, appropriate regulations and interpretations. Coordinates, reviews, and may prepare reports for submission.

About the Role

#LI-Hybrid

Key Responsibilities:

- Is responsible for implementing regulatory strategy and managing operational activities for assigned major/ large regions.
- Provides input into global regulatory strategy and contributes to Regulatory Functional Plan (RFP) and Seed Document, or their equivalents, including identification of gaps or risks in global strategic plan for assigned regions.
- Partners with regions to align on regulatory strategy in order to fulfil business objectives -Implements RFP across assigned regions.
- Determines requirements and sets objectives for Health Authority (HA) interactions with DRA GPT representative and/or GTAL.
- Facilitates preparation and finalization of briefing books and contributes to preparation of summary documents.
- Develops and implements plans for timely response to HA requests and coordinates responses.
- May serve as local HA liaison depending on location (e.g., FDA or EMA).
- Drives coordination, planning, and submission of dossiers in assigned regions worldwide.
- Reviews, approves and submits Clinical Trial Applications (CTAs) and Investigational New Drugs (INDs).
- Responsible for facilitating timely submission and approval of dossier with HAs under the guidance of the DRA GPT representative and/or GTAL.

Essential Requirements:

- Science based BS or MS with requisite experience and (Minimum/desirable): demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred.
- Strong knowledge of regulatory submission and approval processes in 1 or more major regions.
- Experience leading regulatory submissions and approvals in at least 1 major region.
- Experience in a global/matrix environment or cross- functional teams in the pharmaceutical industry Experience in HA negotiations.
- 4-6 years involvement in regulatory drug/biologic development spanning activities in Phases I-IV in the following areas:
    - Innovation in regulatory strategy.
    - Prior history with post-marketing/brand optimization strategies and commercial awareness preferred.
- Involvement in dossier submissions and approvals. o HA negotiations
- Drug regulatory submissions and commercialization in major regions.
- Proven ability to analyze and interpret efficacy and safety data.
- Regulatory operational expertise.

The pay range for this position at commencement of employment is expected to be between $145,600 and $270,400 /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

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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.

部門
Development

部門
Universal Hierarchy Node

国
USA

State
New Jersey

勤務地
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work

No

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