Global Program Regulatory Manager

Job ID
REQ-10036571
Ene 23, 2025
Estados Unidos

Resumen

The IB&GH Development Unit portfolio covers a wide range of indications, such as Neglected Tropical Diseases, Sickle cell Disease, Transplant and immunology, Oncology, Cardiovascular, and Ophtha. The products in the portfolio range from early-stage development to mature in-market brands.
As Global Program Regulatory Manager, you will work with the support of a RA Program Lead to develop and implement the global regulatory strategy for program(s) through development, registration and post approval in the assigned region(s).

The Global Program Regulatory Manager is also a member of the RA sub team and may lead or represent RA in regional or cross functional teams.

About the Role

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 bachelors degree, plus an understanding of pharmaceutical development, clinical trials
- Track record of involvement in regulatory or pharmaceutical development, in one or more major regions
- Strong interpersonal skills and experience working in a complex, cross functional organization and leading cross function teams
- Compliance and Quality mindset

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

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EEO Statement:

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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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