Global Program Regulatory Manager (Remote)

Job ID
REQ-10054883

10月 12, 2025

USA

摘要

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-Remote

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 ideal location for this role is East Hanover, NJ site, where hybrid working principles apply. A distant working arrangement may be considered in certain states for US associates who are not within a daily commutable distance (more than 50 miles one way). Distant workers are responsible for the cost of home office expenses and periodic travel/lodging to East Hanover, NJ site, as

determined necessary by hiring manager.

The salary for this position is expected to range between $114,100 and $211,900 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days,
holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people click here.

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. 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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Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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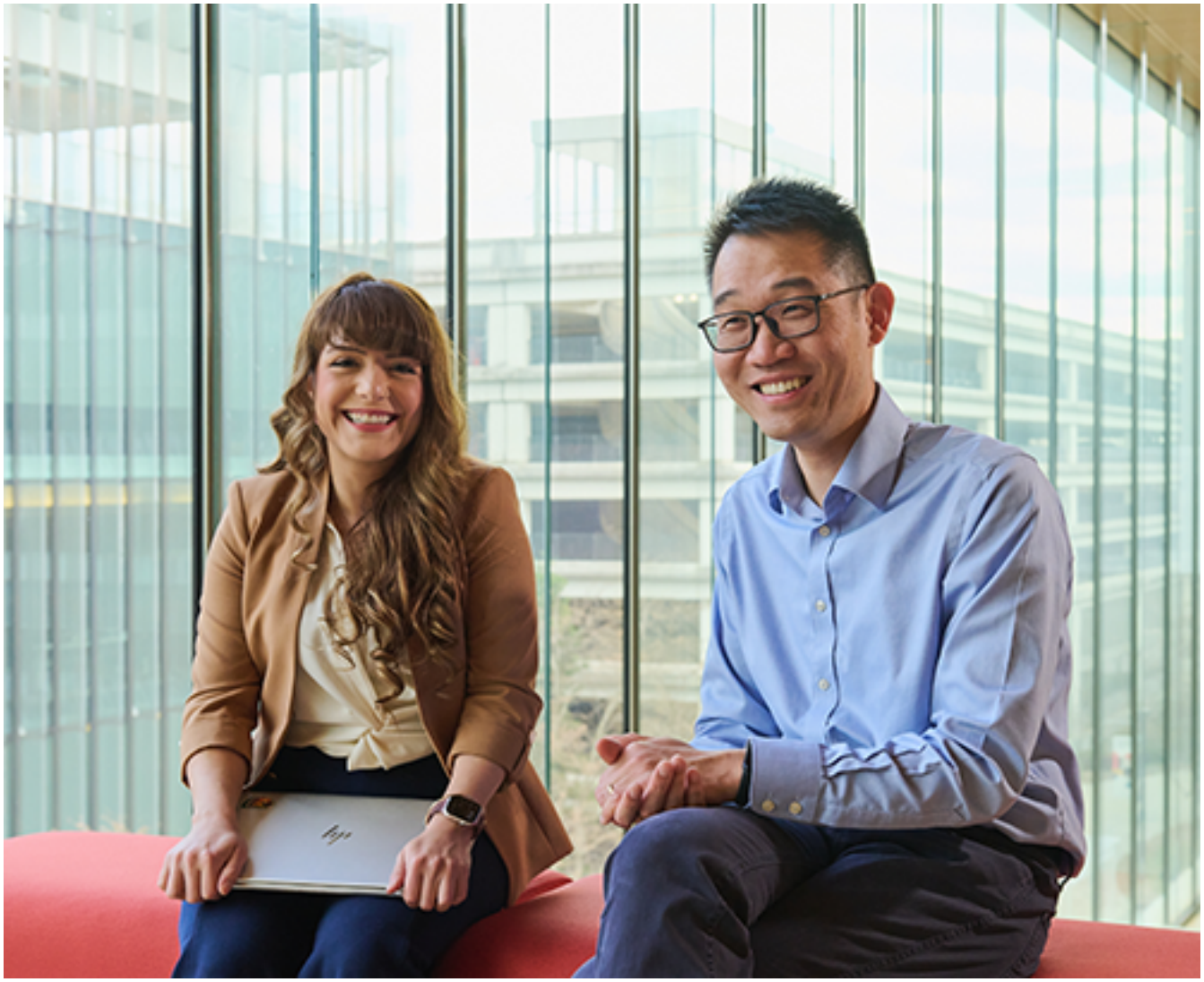

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