

Senior Global Program Regulatory Manager (Early Development) - Associate Director Level

Job ID
REQ-10048241

4月 16, 2025

USA

摘要

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.

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.
- 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).
- Contributes to and often leads the development of departmental goals and objectives.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

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 and 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>

Skills:

- Clinical Trials.
- Cross-Functional Teams.
- Detail Oriented.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- Problem Solving Skills.
- Regulatory Compliance.
- Risk Management.

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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.

部门

Development

Business Unit

Innovative Medicines

地点

USA

状态

Massachusetts

站点

Cambridge (USA)

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1

East Hanover, New Jersey, USA

Functional Area

Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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