Global Regulatory Affairs Associate Director (Senior Global Program Regulatory Manager)

Job ID
REQ-10053743

9月 02, 2025

United Kingdom

摘要

#LI-Hybrid (3 days per week on-site)
Location: London (The Westworks), United Kingdom or Dublin, Ireland
Internal Job Title: Senior Global Program Regulatory Manager

We are looking for an experienced and proactive Senior Global Program Regulatory Manager to join our Global Regulatory Affairs team.The role involves directing the development and submission of regulatory documents, providing strategic direction and negotiating with agencies to expedite approvals. It also ensures timely approval and compliance of new and marketed products, and serves as a regulatory liaison throughout the product lifecycle.

About the Role

Major accountabilities:

- Lead the implementation of regulatory strategies and operational activities across major global regions.
- Provide strategic input into global regulatory plans, identifying risks and contributing to key planning documents.
- Align regional regulatory approaches with global objectives through collaboration with cross-functional and regional teams.
- Define and manage Health Authority (HA) interaction strategies, including preparation of briefing materials.
- Oversee the planning, coordination, and submission of regulatory dossiers (e.g., CTAs, INDs, Risk Management Plans).
- Serve as a liaison with local HAs (e.g., FDA, EMA) and lead or support negotiations for regional approvals.
- Develop and implement strategies to minimize review delays and regulatory clock stops.
- Ensure timely and compliant responses to HA queries and requests.
- Contribute to departmental goal setting and lead initiatives to improve regulatory processes.
- Ensure adherence to internal policies, SOPs, and global regulatory requirements.

Minimum requirements:

- Bachelor ' s or Master ' s degree in Life Sciences, Pharmacy, or a related field.
- Significant experience in regulatory affairs within the pharmaceutical industry.
- Proven track record in project management and regulatory operations.
- Experience representing the organization in cross-functional and cross-cultural settings.
- Strong knowledge of clinical trials, drug development, and regulatory compliance.
- Excellent problem-solving, negotiation, and communication skills.
- Detail-oriented with the ability to manage complex regulatory projects.
- Skilled in risk management and working with cross-functional teams.
- Ability to navigate and influence Health Authority interactions.
- Fluency in English (written and spoken) is essential.

Commitment to Diversity and Inclusion/EEO

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

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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部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Dublin (NOCC), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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