Global Regulatory Affairs Director (Global Program Regulatory Director)

Job ID
REQ-10051471

Jun 09, 2025

United Kingdom

Summary

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

Novartis is seeking a Global Program Regulatory Director (GPRD) to lead global regulatory strategies for development and marketed products. This role integrates inputs from health authorities and stakeholders to meet commercial and portfolio objectives. The GPRD identifies regulatory opportunities, develops contingencies, ensures strategy execution, leads regulatory subteams, and represents Regulatory Affairs on program and cross-functional teams.

About the Role

Major accountabilities:

- Create high-quality global regulatory strategies and manage Health Authority interactions to achieve development and business objectives.
- Identify and communicate potential regulatory opportunities and risks, and develop mitigation strategies.
- Utilize regional expertise to define and execute global regulatory strategies and engage with Health Authorities.
- Offer strategic regulatory input on key development, labeling, and promotional documents.
- Oversee submission planning, guide contributing authors, and critically review submission documentation.
- Lead interactions with regulatory and development management and external consultants for strategic input.
- Provide strategic regulatory and development input into Business Development & Licensing due diligence evaluations.
- Maintain compliance with global regulatory requirements and internal policies, and coordinate regulatory compliance activities.
- Lead regulatory teams, provide feedback and coaching, and support the growth and development of subteam members.
- Manage regulatory submissions, portfolio transformation activities, and business and operational excellence tasks.

Minimum requirements:

- Bachelor's or Master's in a science-based field; advanced degrees preferred.
- Fluent in English; additional languages are a plus.
- Significant experience in regulatory and pharmaceutical development (Phases I-IV).
- Expertise in regulatory strategy, scientific data analysis, and HA guidance.
- Significant experience with major submissions.
- Knowledge of post-marketing strategies and commercial awareness.
- Proven regulatory operations and compliance skills.
- Strong leadership and matrix management abilities.
- Excellent communication, influencing, and problem-solving skills.
- Ability to navigate organizational complexity effectively.

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

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

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部門
Development

部門
Universal Hierarchy Node

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United Kingdom

勤務地
London (The Westworks)

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

Alternative Location 1
Dublin (NOCC), Ireland

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

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