Global Regulatory Affairs Director (Cardio-Metabolic)

Job ID REQ-10064003

11月 12, 2025

United Kingdom

摘要

Office Location: London (The Westworks), United Kingdom #LI-Hybrid Hybrid (12 days per month on-site if living within 50 miles to our London office) #LI-Remote Remote (if living beyond 50 miles to our London office) 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

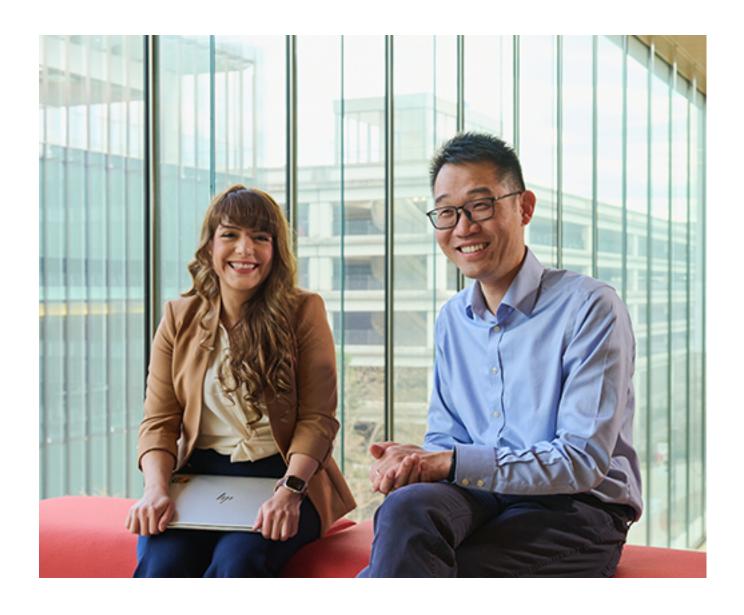
Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards
部门 Development
Business Unit Development
地点 United Kingdom
站点 London (The Westworks)
Company / Legal Entity GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1 Home Worker, United Kingdom
Functional Area Research & Development
Job Type Full time
Employment Type Regular

Shift Work

No

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