

# Global Regulatory Affairs Associate Director (Cardio-Metabolic)

Job ID REQ-10064681

11月 05, 2025

**United Kingdom** 

## 摘要

#LI-Hybrid (12 days per month on-site)
Location: London (The Westworks), United Kingdom or Dublin, Ireland

We are looking for an experienced and proactive Global Regulatory Affairs Associate Director Cardio-Metabolic 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 crossfunctional 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

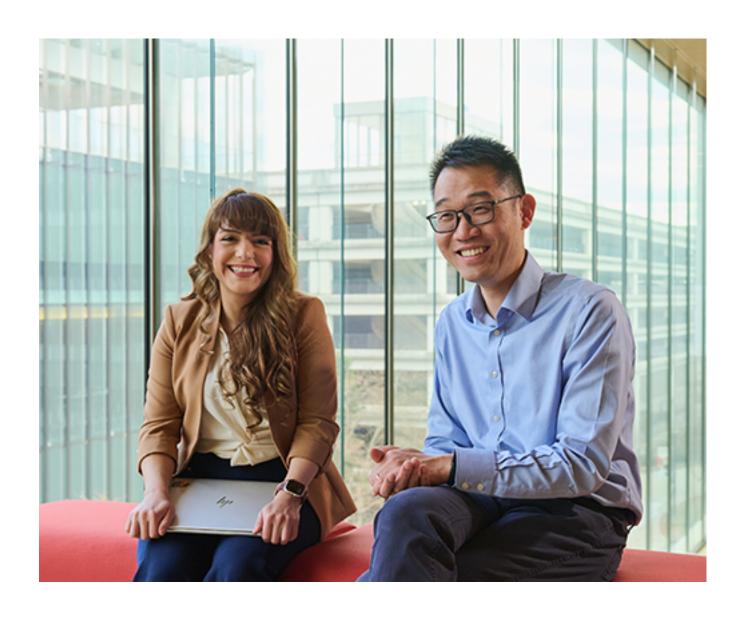
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部门 Development
Business Unit Universal Hierarchy Node
地点 United Kingdom
站点 London (The Westworks)
Company / Legal Entity GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area Research & Development
Job Type Full time
Employment Type Regular
Shift Work No
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