

Global Regulatory Affairs Manager (Global Program Regulatory Manager)

Job ID
REQ-10051589

6月 09, 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: Global Program Regulatory Manager

We are looking for an experienced and proactive Regulatory Affairs Manager to join our Global Regulatory Affairs team. This role is critical in driving regulatory strategy and managing operational activities across key regions. You will collaborate with cross-functional teams to ensure timely submissions, approvals, and compliance with global regulatory requirements, supporting the successful development and commercialization of pharmaceutical products.

About the Role

Major Responsibilities:

- Implement regional regulatory strategies in alignment with global objectives.
- Contribute to global regulatory planning and identify strategic gaps or risks.
- Lead or support Health Authority (HA) interactions, including briefing material preparation.
- Coordinate timely and compliant regulatory submissions across assigned regions.
- Review and approve Clinical Trial Applications (CTAs), Investigational New Drugs (INDs), and Risk Management Plans.
- Act as a liaison with local HAs (e.g. FDA, EMA) as required.
- Ensure timely and effective responses to HA queries and requests.
- Collaborate cross-functionally to align regulatory plans with business goals.
- Monitor and ensure compliance with internal policies and external regulations.
- Support or lead negotiations for regional approvals to meet project timelines.

Essential Requirements:

- Bachelor ' s or Master ' s degree in Life Sciences, Pharmacy, or a related field.
- Proven experience in regulatory affairs within the pharmaceutical industry.
- Strong understanding of drug development and clinical trial processes.
- Experience in managing regulatory submissions and HA interactions.

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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