International Regulatory Affairs Director (International Program Regulatory Director)

Job ID
REQ-10053053

7月 04, 2025

United Kingdom

摘要

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

Novartis is seeking an International Program Regulatory Director to join our dynamic team. The IPRD will play a crucial role in providing strategic support and oversight to our global and regional teams. This position involves designing and executing optimal registration strategies and plans for our assigned portfolio across various international markets.

About the Role

Key responsibilities:

- Sets up and manages the International RA subteam comprised of global and country RA roles from countries in scope with the objective of generating optimal registration strategies, ensure their inclusion into global plans and their efficient execution.
- Drives the process of registration plan design, alignment and sign off with relevant regulatory, commercial and stakeholders in global, region and countries.
- Oversees the up to date maintenance and execution of registration plans for all international countries, including procurement of ancillary document for submission dossier, review of and contribution to responses to Health Authority (HA) questions, follow up on key milestone activities by relevant stakeholders.
- In alignment with Development Unit (DU) RA and RA transactions team, may provide specific support to integration assets for international countries.
- In partnership with DU RA roles, is responsible to generate overviews of pipeline programs and to disseminate them to relevant international stakeholders to support strategic and operational planning.
- Partners with global,regional and country RA roles on regulatory emerging new regulatory policies and requirements and ensures their optimal interpretation and use in project strategies and implementation plans. Is accountable the up to date maintenance of repositories of country requirements and dissemination of information to relevant stakeholders.
- Takes a leading role in designing and actioning registration plans for Emerging Markets Brand and acts as main contact point within RA INT for the Emerging Brands Center of Excellence for the portfolio in scope.
- In alignment with relevant DU, may act as lead RA role on the registration of products that target diseases which are predominantly prevalent in international countries.
- Support the execution of, or act as a region representative in functional or cross-functional initiatives, particularly those with potential impacts on international RA resources or FTE allocations.
- Mentors International Program Regulatory Managers and Sr. Managers on ways of working on pipeline management ensuring compliance with Novartis quality standards. In partnership with the operational manager, identify and facilitate growth and development opportunities, supporting a culture of continuous learning.

Essential Requirements:

- Fluency in English as a business language.
- Science based BS or MS with requisite experience and demonstrated capability.
- Experience with country, regional or global Regulatory Affairs and product development.
- Proven track record of HA negotiations.
- Solid expertise in project management.
- Ability to develop and communicate strategic vision.
- Ability to work in cross-functional environment.
- Experience of early recognition of potential regulatory issues, complex situations, sound risk assessment and overcoming hurdles.

Desirable Requirements:

- Advanced degree (e.g., MD, PhD, PharmD) preferred.

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.

Functional Area

Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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