International Regulatory Affairs Associate Director (Senior International Program Regulatory Manager)

Job ID
REQ-10057262

7月 08, 2025

United Kingdom

摘要

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

Novartis is seeking an International Program Regulatory Director to join our dynamic team. The Senior IPRM will support the design and execution of optimal
registration strategies and plans for the assigned portfolio in the assigned International countries.

About the Role

Major accountabilities:

- Drives the execution of registration plans as defined in the International RA subteam and in partnership with the countries, regional roles and global line functions.
- Drives the design, 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.
- Supports the International Program Regulatory Director (IPRD) in partnering with Development Units (DU) RA roles to obtain, digest and communicate efficiently pipeline information to relevant stakeholders.
- Drives updates to the country requirements and registration plans are performed timely and the necessary quality.
- Supports and implements initiatives to enhance efficiency in ways of working and functional excellence.
- Supports the IPRD in the design and execution of plans for Emerging Markets Brands and may interface with the Emerging Markets Brands Center of excellence for assigned projects.
- Supports the IPRD in designing and executing registration plans for products that target diseases which are predominantly prevalent in INT countries.
- Partners with groups on geographic expansion plans and execution for international countries.
- Drives the dissemination of information to and education of global roles on international country/regional requirements.
- 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.
- May act as deputy of IPRD on assigned programs.

Essential Requirements:

- Fluency in English as a business language.
- Experience in Regulatory, product development
- Country, regional or global Regulatory Affairs experience.
- Proven track record of HA negotiations
- Ability to develop and communicate strategic vision.
- Proven track record of early recognition of potential regulatory issues, complex situations, sound risk assessment and overcoming hurdles.
- Expertise in project management.
- Ability to work in cross-functional environment.

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

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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