International Program Regulatory Director

Job ID
REQ-10061871

10月 06, 2025

United Kingdom

摘要

The International Program Regulatory Director (IPRD) is responsible for providing strategic support and oversight to global and regional teams on the design and execution of optimal registration strategies and plans for the assigned portfolio in the assigned International countries.

By partnering efficiently with relevant global DU line functions (LF) and International (INT) cross functional stakeholders, the IPRD drives the process of registration plan design, alignment and sign off with relevant regulatory, commercial and DU stakeholders in global, region and countries in INT markets except for China, Japan and the European Union. The IPRD ensures the timely dissemination of consolidated plans to the relevant global and INT stakeholders.

The IPRD uses global, regional and country sources to ensure the maintenance of country requirements, pipeline information and registration plans across all INT markets and their efficient communication to INT stakeholders. They partner with relevant line functions to optimally translate new requirements into tangible NVS plans. IPRD leads and oversees the implementation of initiatives to enhance efficiency in ways of working and functional excellence.

The IPRD is member of the global RA subteam and leads the INT RA subteam of assigned countries.

They may lead or contribute to regional cross-functional initiatives and committees and may represent International RA in global cross-functional initiatives and committees. The IPRD may act as deputy to the Regulatory Head Pipeline Management, Compliance and Operations.

About the Role

Major accountabilities:

- Sets up and manages the INT 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. Represents countries in scope of the INT subteam at the global RA subteam level.
- Upon notification letter dispatch and for major updates thereafter, the IPRD drives the process of registration plan design, alignment and sign off with relevant regulatory, commercial and DU stakeholders in global, region and countries in all INT markets except for China, Japan and the European Union. Is accountable for the appropriate dissemination of agreed plans to relevant stakeholders in the organization.
- Oversees the up to date maintenance and execution of registration plans for all INT countries in alignment with RA INT and RA DU, 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 RA and LF stakeholders. Maintain up to date contact CO contact lists for programs and COs in scope.
- In alignment with DU RA and RA transactions team, may provide specific support to integration assets for INT countries.
- In partnership with DU RA roles (GPRDs, GRTLs), is responsible to generate overviews of pipeline programs and to disseminate them to relevant INT stakeholders to support strategic and operational planning.
- Partners with global LFs and Regional / 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.
- IPRD leads and oversees the implementation of initiatives to enhance efficiency in ways of working and functional excellence.
- 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 INT countries.
- Partners with GRSS&C LCM group on geographic expansion plans and execution for INT countries.
- Partners with RA INT roles and global policy on identification & shaping of policy changes in INT countries.
- Oversees dissemination of information to and education of global roles on INT 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 INT RA resources or FTE allocations.

- Mentors International Program Regulatory Managers and Sr. Managers on ways of working on pipeline management ensuring compliance with NVS quality standards. In partnership with the operational manager, identify and facilitate growth and development opportunities, supporting a culture of continuous learning.
- May participate in recruitment of IPRM/D associates and their development.
- Champion Novartis culture, values and behaviors and demonstrate behaviors in action in-line with Novartis leadership expectations. May act as deputy of RA Head Pipeline Management, Compliance and Operations.

Key performance indicators:

- Meets objectives as defined in registration plans for the countries and portfolio in scope.
- Proof of maintenance and communication of country requirements and registration plans for INT countries.

Minimum Requirements:
Education and Work Experience:

- Science based BS or MS with requisite experience and demonstrated capability.
- Advanced degree (e.g., MD, PhD, PharmD) preferred.
- Minimum of 8 years in Regulatory, product development
- Minimum of 2 years country, regional or global Regulatory
- Proven track record of HA negotiations
- Ability to develop and communicate strategic vision
- Ability to work in cross-functional environment
- Proven expertise in project management
- Highly committed and team oriented
- Proven strong leadership skills
- Proven track record of early recognition of potential regulatory issues, complex situations, sound risk assessment and overcoming hurdles
- Strong team player
- Proven track record of successful risk assessment
- High level of organizational awareness
- Ability to travel and represent the organization
- Fluency in English as a business language. *Additional language is an asset.*

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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