International Program Regulatory Manager (IPRM)

Job ID
REQ-10058981

7月 28, 2025

India

摘要

The International Program Regulatory Manager (IPRM) works under supervision of the International Program Regulatory Director (IPRD) and in partnership with international regulatory teams and global line functions to provide input into registration strategies and to drive the timely execution of registration plans for the assigned portfolio in the assigned International (INT) countries. They are accountable to recognize and resolve high priority topics to ensure timelines and objectives of registration plans are met.
The IPRM uses global, regional and country sources to maintain the relevant databases on country requirements, pipeline information and registration plans across all INT markets and to disseminate relevant information to INT stakeholders. The IPRM supports and implements initiatives to enhance efficiency in ways of working and functional excellence.
The IPRM may act as deputy of the IPRD on global RA sub teams. The IPRM may contribute to regional cross-functional initiatives

About the Role

Key Responsibilities

- Provides input into registration strategies for INT countries and drives the execution of registration plans as defined in the INT RA subteam and in partnership with the countries, regional roles and global line functions as applicable including procurement of ancillary documents for submission dossier, contribution to responses to Health Authority (HA) questions, follow up on key milestone activities by relevant RA and line function stakeholders. Maintain up to date contact country contact lists for programs and countries in scope.
- Supports the IPRD in partnering with DU RA roles to obtain, digest and communicate efficiently pipeline information to relevant stakeholders. Ensures updates to registration plans are performed timely and with the necessary quality
- IPRM supports and implements initiatives to enhance efficiency in ways of working and functional excellence.
- Supports the IPRD in the execution of plans for Emerging Markets Brands for assigned projects.
- Supports the IPRD in the execution of registration plans for products that target diseases which are predominantly prevalent in INT countries.
- Supports the IPRD in the execution of geographic expansion plans for INT countries.
- Drives the dissemination of information to and education of global roles on INT country/regional requirements.
- Support the implementation of functional or cross-functional initiatives, particularly those with potential impacts on INT RA resources or FTE allocations.
- May act as deputy of IPRD on assigned programs

Minimum Requirements :

- Degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Minimum of 2 years in Regulatory affairs in a country, regional or global regulatory setting
- Experience in regulatory license maintenance and new product registrations
- Ability to work in cross-functional environment
- Experience in project management
- Highly committed and team oriented
- Ability to recognize potential regulatory issues, complex situations, sound risk assessment and overcoming hurdles
- Strong team playerExperience in successful risk assessment, Organizational awareness

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部门
Development

Business Unit
Universal Hierarchy Node

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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