

Senior International Program Regulatory Manager (Sr. IPRM)

Job ID
REQ-10056343
Jun 30, 2025
India

Summary

The senior International Program Regulatory Manager (Sr. IPRM) works under limited supervision of the International Program Regulatory Director to support the design and execution of optimal registration strategies and plans for the assigned portfolio in the assigned International countries.

By partnering efficiently with International Program Regulatory Directors, global DU and International (INT) regulatory stakeholders, the Sr. IPRM supports optimal pipeline planning accounting for regional priorities and efficient use of regulatory paths for acceleration in assigned countries. They support the timely execution of registration plans by the relevant line functions and the resolution of high priority topics.

The Sr. 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. Sr. IPRM supports and implements initiatives to enhance efficiency in ways of working and functional excellence.

The Sr. IPRM is a member of the INT RA subteam and may act as deputy of the IPRD on global RA subteams. The Sr. IPRM may lead or contribute to regional cross-functional initiatives and committees.

About the Role

Key Responsibilities

- Drives the execution of registration plans as defined in the INT RA subteam and in partnership with the countries, regional roles and global LFs as applicable.
- Drives the design, 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.
- Supports the IPRD in partnering with 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. Sr. IPRM 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 GRSS&C LCM group on geographic expansion plans and execution for INT countries. Drives the 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. May act as deputy of IPRD on assigned programs.
- 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:

- Minimum of 6 years in Regulatory, product development, minimum of 1 year's 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 matrix 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, Organizational awareness
- Ability to travel and represent the organization
- Degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Desirable: Advanced degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

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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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>

Division

Development

Business Unit

Universal Hierarchy Node

Location

India

Site

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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