NOVARTIS

Global Program Regulatory Manager (GPRM)

Job ID
REQ-10073867
апр 16, 2026
Индия

Сводка

The Global Program Regulatory Manager (GPRM) works under the supervision of the regulatory affairs (RA) program lead to develop and implement the global regulatory strategy through development, registration and post approval in the assigned region(s).
The GPRM is a member of the RA sub team and may lead or represent RA in regional or cross-functional teams.

About the Role

Key Responsibilities

- Regulatory Strategy- Provides input to global program regulatory strategy, including regulatory designations & innovative approaches
- Coordinates regulatory readiness with other line functions, Country Organizations & regions ,
- Represents RA or leads regional or cross-functional activities, provides strategic input to cross functional deliverables (e.g. protocols, IB, safety reports etc)
- Contributes to the development and maintenance of the Core Data Sheet (CDS)
- Determines requirements and coordinates activities for Health Authority (HA) interactions. May facilitate HAs meetings together with RA program lead. May serve as local HA liaison (e.g., FDA or EMA).
- Regulatory Submissions-Leads planning, preparation and submission of clinical trials.
- Leads implementation of the defined global registration strategy into regional submissions worldwide by country organizations.
- Coordinates, plans, and prepares for submission of initial registration and post-approval applications, including authoring of Module 1 documents, contributes to preparation, review and maintenance of local product information in their assigned region
- Leads regulatory activities during HA reviews including response to questions and HA interactions. Regulatory Excellence and Compliance-Ensures timely RA input and submission of regulatory compliance and maintenance reports (e.g. aggregate safety reports, annual reports, renewals, etc) across assigned regions. Maintains regulatory information in compliance databases and document management systems

Essential requirements

- Science based BS or MS. Advanced degree (e.g., MD, PhD, PharmD, regulatory) preferred
- Understanding of pharmaceutical development, clinical trials, analysis and interpretation of scientific data
- ≥2 years involvement in regulatory and pharmaceutical development in 1 or more major regions
- Experience in working in cross-functional teams
- Strong collaboration and communication, problem solving skills.
- Basic organizational awareness (e.g., interrelationship of departments, business priorities).
- Compliance and Quality mindset

Desirable Requirements: Global program regulatory strategy,

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Индия
Сайт
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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