

Global Program Regulatory Manager (GPRM)

Job ID

REQ-10073867

Apr 16, 2026

LOC_IN

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

Role Requirements

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 \(PDF 30 MB\)](#)

Division

DIV_GD

Business Unit

Development

Location

LOC_IN

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

FCT_RD

Job Type

Full time

Employment Type

Regular

Shift Work

No

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