NOVARTIS

Global Regulatory Submission Manager

Job ID
REQ-10073777
апр 16, 2026
Индия

Сводка

Ensures a controlled documentation system, record retention, and information services including electronic records retention processes in accordance with regulatory requirements. Ensures compliance to the requirements from regulatory agencies. Maintains the technical and non-technical documentation change system. Assures procedures are in place to classify and maintain records. Interprets and enforces all documentation formatting, standards, policies, and operating procedure requirements. May identify submission components, communicate documentation standards and coordinate assembly of regulatory dossiers. May analyze and evaluate data, extract pertinent information, prepare information abstracts and executive summaries of material searched. May maintain extensive knowledge of product information and continuous contacts with local, regional, and divisional customers.

About the Role

Key Responsibilities

- Manages multiple, large and complex global regulatory submission projects.
- Develop and provide submission and contribute to the technical related regulatory strategy, intelligence and knowledge required to develop, register, and maintain global products.
- Contribute to strategic and technical input/support to drive implementation of global systems, tools and processes to support global development projects and/or marketed products.
- A seasoned, experienced professional with a full understanding of area of specialization; resolves a wide range of issues in creative ways.
- This job is the fully qualified, career-oriented, journey-level position .
- Works on problems of diverse scope where analysis of data requires evaluation of identifiable factors. Demonstrates good judgment in selecting methods and techniques for obtaining solutions.
- Networks with senior internal and external personnel in own area of expertise.
- Contributes to many cost center goals and objectives; may contribute to service line goals -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Essential Requirements

- BS in Life Sciences or a relevant discipline with at least 5 years of professional work experience. Masters degree preferred
- 3-5 years of Regulatory Affairs or Regulatory submission related experience.
- Experience with global regulatory submission formats, including familiarity with submission publishing activities, familiar with the drug development process.
- Effective interpersonal skills, strong written and oral communication and presentation skills.
- Solid project management, organizational and time management skills to manage multiple ongoing projects simultaneously.
- Familiar with global Health Authority regulations/guidances eg., FDA regulations, ICH and EMA guidelines/directives.
- Works independently and with minimal supervision. Proficiency with computer programs/systems (MS office, etc.) with demonstrated ability to learn new systems quickly. Strong analytical skills and problem solving skills.
- Ability to coordinate and work effectively with cross-functional teams.

Desirable Requirements: global regulatory submission projects.

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
Alternative Location 1

Telangana, Индия
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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