NOVARTIS

Global Regulatory Submission Manager

Job ID
REQ-10078004
май 13, 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

• Drives cross-functional teams focused on the planning, compilation and dispatch of worldwide regulatory submissions, anticipating technical obstacles and developing solutions. Manages multiple and simultaneous global regulatory submission projects in eCTD and non-eCTD format [e.g., NDA/BLA/INDs, MAAs (CP, MRP, Nees), HA AtoQ, Compliance submissions, etc.].
• Provides guidance to project teams related to worldwide HA submission structure/format/requirements, submission filing strategy, eCTD document lifecycle management and submission compilation workflows.
• Tracks timely delivery of submission components, coordinates submission publishing activities with publishing team and organizes internal review and approvals.
• Partners with cross functional groups across the organization and contributes to operational activities and ongoing initiatives.
• Effectively troubleshoots technical/quality issues relating to compilation, validation and dispatch of global submission outputs.
• Assesses publishing resource and support needs and develops/implements solutions to create efficiencies.

Minimum Requirements:
• 3-5 years of Regulatory Affairs or Regulatory submission related experience. BS in Life Sciences or a relevant discipline with at least 5 years of professional work experience. Master's degree preferred
• 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/guidance 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

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

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.

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