NOVARTIS

Assistant Manager - RA

Job ID
REQ-10077465
май 12, 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 & 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

- Lead compilation and submission of regulatory dossiers for new drugs, line extensions, additional indications, and lifecycle changes (renewals, site registrations, production transfers).
- Manage Clinical Trial Application (CTA) submissions and ensure compliance throughout study lifecycle.
- Support development and execution of regulatory strategies for pipeline products to enable timely market access.
- Ensure timely execution of post-approval regulatory commitments including PSURs, CMC variations, and labeling updates.
- Drive regulatory compliance tracking, including monitoring submissions, approvals, and ongoing obligations with Health Authorities.
- Collaborate with cross-functional stakeholders (Legal, QA, Supply Chain, Global teams) to ensure seamless regulatory execution and supply continuity.
- Support critical regulatory changes (e.g., site changes, legal entity updates, supply chain changes) with minimal disruption to business.
- Contribute to regulatory intelligence gathering and provide guidance on evolving regulatory requirements.
- Ensure data integrity and compliance through maintenance of regulatory databases and audit readiness.
- Drive process improvements, CAPA management, and compliance oversight to enhance regulatory efficiency and inspection readiness.

Essential Requirements

- Bachelor’s degree in Pharmacy / Life Sciences / Health Sciences/ Chemistry.
- 5 + years of hands-on experience in Regulatory Affairs within Indian regulatory framework, preferably in a multinational pharmaceutical environment.
- Strong experience in dossier compilation and HA submissions (NDAs, CTAs, lifecycle management).
- Good understanding of Indian regulatory requirements (e.g., CDSCO processes, clinical trial regulations, post-approval compliance).
- Strong cross-functional collaboration and stakeholder management skills.
- Effective communication (written and verbal) and interpersonal skills.

Desirable Requirements

- Post-graduate degree in Pharmacy / Life Sciences / Regulatory Affairs/ Chemistry.
- Exposure to global regulatory environments or working with HQ/overseas teams.
- Experience in regulatory strategy planning for new product launches.

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
Mumbai (Head 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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