Sr Regulatory Coordinator

Job ID
REQ-10055990

7月 29, 2025

India

摘要

The Senior Regulatory Coordinator (Sr. RC) works under close supervision to support for development including line extension and /maintenance projects through development, registration, and approval including post approval commitments.

To maximize operational effectiveness, Collaborate with RA GDD Development Units, RA GDD CMC, Regional Representatives (MoW, LACan, EU, China, Japan), Novartis Technical Operations (NTO), and Quality Assurance to align on planning, execution, communication, and completion of assigned projects.

About the Role

Key Responsibilities

- Ensure procurement of various key regulatory components (e.g. ordering certificates, GMP,

registration samples, COA ' s and other regulatory documents as per the needed) to achieve marketing authorization and life cycle maintenance in collaboration with following internal and external stakeholders: NTO, Reg CMC, Global labelling & RA Ops for renewals, SCM, Tech Ops for Regulatory samples, HA such as USFDA, Swiss medic/EMA & Consular Services for certificates etc, External Service providers
- Support for planning and management of timely delivery of critical regulatory materials (registration samples) and various regulatory authorized documents (certificates) for product license renewals, manufacturing site transfers & new registration submissions word wide (as per health authority requirements).
- For new submissions - Represents Regulatory Affairs LCM BOE team in in NTO project team meetings, RA global and regional team meetings.
- Organize regulatory readiness with relevant line functions and with Country Organizations & Regions for timely delivery of submission and approvals
- Track progress of assigned projects, including timelines and dossier deliveries.
- Ensure quality and compliance with global regulatory requirements, countries requirements and adherence to regulatory internal policies and processes
- Support for maintaining country requirement lists and conducting need-based surveys & interaction with country organizations.
- Contribute to non-project related initiatives and excellence activities
- Support lessons learned sessions and trainings within and external to RA GDD leading to improve strategies and decisions on common regulatory approaches.

Minimum Requirements:

- Degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Minimum of 3-5 years of experience in Regulatory Affairs, related areas of the pharmaceutical Industry
- Good interpersonal and communication skills
- Ability to plan and prioritize work
- Ability to work effectively in a matrix environment
- Fluency in English - written and spoken

Why Novartis:
Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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Novartis is committed to working with and providing reasonable accommodation to individuals with

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部门
Development

Business Unit
Universal Hierarchy Node

地点
India

站点
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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