Regulatory Coordinator

Job ID
REQ-10063144

9月 30, 2025

India

摘要

Contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Supports all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

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

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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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