

Regulatory Coordinator

Job ID
REQ-10084807
июл 30, 2026
Индия
Available in: English

Сводка

The Regulatory Coordinator (RC) works under close supervision to provide operational and compliance support for assigned development, line extension, and lifecycle management projects, including registrations, approvals, post-approval commitments, and production transfer initiatives driven by Novartis Technical Operations (NTO).

The RC collaborates closely with RA GDD Development and CMC teams, regional stakeholders (MoW, LACan, EU, China, Japan), NTO, and Quality Assurance to align planning, execution, communication, and successful completion of assigned projects.

About the Role

Major Accountabilities

- Ensure timely procurement of critical regulatory components (e.g., CPP, GMP certificates, registration samples, CoAs, and other regulatory documents) to support marketing authorization and lifecycle maintenance, in collaboration with internal functions (NTO, Reg CMC, RA Ops, Global Labelling, SCM, Tech Ops) and external stakeholders (Health Authorities, Consular Services, service providers).
- Coordinate regulatory readiness with line functions, Country Organizations, and Regions to enable on-time submissions and approvals.
- Act as single point of contact for Regulatory Affairs in projects and governance forums (eg. NTO project teams and global/regional forums)
- Provide regulatory input on requirements, timelines, and risks for submissions and transfers.
- Proactively identify, manage, and communicate regulatory risks and mitigations.
- Track and manage project progress, including timelines, dossier deliverables, and regulatory milestones.
- Ensure quality and compliance with global and country-specific regulatory requirements, and adherence to internal policies and processes.
- Demonstrate contribution to strengthen country intelligence, stakeholder alignment, and knowledge sharing within RA.

Minimum Requirement

- Minimum of 2 years of experience in Regulatory Affairs, related areas of the pharmaceutical Industry
- Strong communication, interpersonal, negotiation, and problem-solving skills
- Proactive, delivery-focused, with flexibility to meet stretch targets
- Demonstrates speed and agility while delivering timely outcomes
- Effectively plans, prioritizes, and manages workload
- Works confidently in a global matrix environment
- Builds strong, effective cross-functional relationship

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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

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