NOVARTIS

Senior Regulatory Coordinator

Job ID
REQ-10092014
Ноя. 12, 2026
Индия

Сводка

The Senior Regulatory Coordinator (Sr. RC) works under close supervision to provide advanced 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 Sr. 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 the single point of contact for Regulatory Affairs, representing RA in NTO project teams and global/regional forums and providing regulatory input on requirements, timelines, and risks for new submissions, LENC, and production transfers.
- Proactively identify regulatory risks, gaps, and trade-offs, and communicate issues, mitigations, and key achievements to project teams to avoid delays.
- 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.
- Contribute to non-project initiatives and continuous improvement activities within RA GDD.
- Drive knowledge sharing and capability building through lessons learned, trainings, and cross-functional engagements to support aligned regulatory strategies.
- Ensure clear alignment on roles and responsibilities across internal and external stakeholders.
- Maintain country requirement intelligence, including requirement lists, surveys, and direct engagement with Country Organizations.

Essential Requirements

- Minimum of 3 years of experience in Regulatory Affairs,related areas of the pharmaceutical Industry
- Strong communication, interpersonal, negotiation,
- and problem-solving skills. Proactive, delivery-focused mindset with flexibility to meet stretch targets.
- Demonstrates agility and speed while maintaining focus on timely outcomes.Effectively plans, prioritizes, and coordinates workloads across teams.
- Works confidently in a global matrix environment across sites and functions.
- Build strong, effective relationships across teams and projects. Regulatory operational expertise.

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.
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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

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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