NOVARTIS

R&D Quality Manager

Job ID
REQ-10051875
May 14, 2025
India

Summary

Independent Project work less complexity, e.g. early phase projects. Lead or support smaller and less complex projects or support more complex projects with mentoring. Higher complex routine tasks e.g. failure investigations and deviation, change controls etc. Manage projects and processes to support departmental portfolio, projects and objectives according to agreed timelines and standards. Ensure that compliance with cGMP is maintained in TRD.

About the Role

Major accountabilities:

- Support a discipline and/or provide a service individually or within a team of associates. May provide functional expertise to Line Unit and other QA Units in area of responsibility
- Write review, decide on approval and/or release of GMP-relevant deliverables and/or related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.
- Manage project related activities (e.g. TRD product portfolio, development of new tools, processes, Quality initiatives, Quality Manual implementation, Quality Plans, Quality Risk Assessments, training activities, qualification and facility upgrade activities, IT validation projects) as per area of responsibility.
- Support Project management functions as a project team member.
- Provide support to TRD line functions in GMP related topics as per area of responsibility.
- Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).

Key performance indicators:

- Coordinate interface issue resolution between business stakeholders and IT subject matter experts
- Serve as deputy to the Business System Owner, providing backup and support for system governance
- Evaluate and approve IRT (Interactive Response Technology) exceptions based on thorough risk assessment to ensure supply continuity
- Review and approve deviations related to clinical supplies, ensuring GxP compliance
- Develop and maintain quality documentation for interface management processes
- Lead cross-functional initiatives to improve system integration and data integrity
- Represent QA in business review meetings and governance forums
- Identify opportunities for process improvement and automation

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?

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Division
Development
Business Unit
Innovative Medicines
Location
India
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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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