

# R&D Quality Manager

Job ID

REQ-10054414

Jun 16, 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

### Key Responsibilities

- 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.).
- Manage a Design History File / Tech File portfolio of assigned Medical Device/ Drug Device Combination projects from Quality perspective and provide functional expertise in responsibility for medical devices and combination products in cross-functional project teams to assure cGMP Compliance with medical device specific regulations (ISO 13485:2016, EU MDR, 21 CFR 820 and 21 CFR Part 4) and internal Novartis standards for Medical Device development products under submission and Life Cycle Management activities. He/She ensures the quality specific tasks of a Design History File and follow-up including supporting medical device reporting to regulatory authorities.
- Monitoring, analysis, and reporting of GMP related KPIs as part of management reporting, Review QA agreements for Medical Device projects. Coordinate complaint investigations for Medical Device projects. Review of release documentation for medical device components.
- Support PMS activities for Medical Device projects. Support QMS and Audit (external and internal) activities

### Minimum Requirements:

- Masters, Bachelor/Technician (> 5 years' pharma)
- Fluent English required (oral & written) Good skills in site (local) language desired.
- Good knowledge of cGMP, working knowledge in technical development, production or QA.
- Sound scientific, technical and regulatory knowledge.
- Good organizational and decision-making skills.
- Good and proven ability to analyze and evaluate cGMP compliance.

#### Commitment to Diversity and Inclusion:

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

#### 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](mailto: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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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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