

Analyst - Quality Operations

Job ID REQ-10026688 Oct 21, 2024 India

Summary

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Major accountabilities:

- 1. Handling of Audit CAPA actions, Deviations and Investigations.
- 2. Preparation of annual audit plans
- 3. Monitoring and maintain of KQI's and KPI's.2.
- 4. Maintenace of Shrepoints and Repositories. •
- 5. Responsible to update the information on SharePoint/ trackers, review the applicable documents for correctness and archival of necessary documents on SharePoint.
- 6. Provide Administrative support in preparation of Quality Management Review meeting slide deck & metrics reporting.
- 7. Preparation, approval, and management of QAA's.
- 8. Develop and maintain process SOPs, working procedures and process maps. •
- 9. Provide support for GMP External Audits and inspection management activities (HA and Self Inspection Audits).
- 10. Maintain Approved supplier list for GxP vendors.
- 11. Preparation of UQAP (Unified Quality Audit Program), Audit preparation support and QARP (Quality assurance responsible Person) Role for audit CAPA Management.

Minimum Requirements:

M.Pharm/ equivalent from a reputed institute.

- Min 4-6 yr Experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ Medical device.
- Basic awareness of GxP compliance requirements. 1/3

Work Experience:

• QMS Knowledge w.r.t. deviations, Investigations, handling of CAPA.

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Division

Operations

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

Nο

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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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