

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.
4. Maintenance of Sharepoints 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

No

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