

Specialist - Quality Operations

Job ID
REQ-10020804

Sep 23, 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

Specialist - Quality Operations

Location - Hyderabad

About the Role:

Provide quality services in compliance with cGMP requirements and Novartis Quality Management

System as defined and agreed between QOP and business partners. Manage Quality aspects & projects within area of responsibility.

Key Responsibilities:

- Coordination and management of analytical method transfers and stability studies. Compilation of data reports
- Life-cycle management of analytical methods, including control of method performance, pharmacopoeia and health authority compliance and definition of method improvements. Handling of deviations, investigation, OOS/OOE/OOT cases as well as changes and complaints
- Perform statistical data analysis to report Out of Expectations (OOE), out of trends (OOT), etc
- SAP master data management: Maintenance of master data, creation of Q-info records and other SAP related activities.
- Validate spreadsheets
- Collect, transcribe and/or compile data from various repositories (SAP, LIMS, external COAs)
- Author, approve and archive Impurity risk assessments - Nitrosamines, residual solvents, etc
- Trend and report all QMS elements as per the request
- Monitor, trend and report Health Safety and Environmental parameters
- Implementation of GMP requirements. Compilation and Review of documents (analytical protocols and reports, annual performance quality reports, ongoing process verification reports, registration documents (Common Technical Document modules)).
- Perform activities of a Quality Control expert as defined by the respective sites
- Support regulatory requirements - routine queries, Chromatogram requests
- Compile Quality performance management decks
- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed

Essential Requirements:

- Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute
- Min 3 years of experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/ medical devices
- GxP knowledge, Basic IT knowledge
- Good communication, presentation and interpersonal skills
- Experience of working closely with the global stakeholders

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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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