

# Specialist – Quality Operations

Job ID

REQ-10015991

Jul 19, 2024

India

## Summary

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.

## About the Role

### Major accountabilities:

- 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

### **Key performance indicators:**

- On-time and GMP-compliant release of dosage forms -No complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand - Successfully support continuous improvement projects -Executes batch release in compliance with registration

### **Minimum Requirements:**

- Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute
- Min 5 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

### **Skills:**

- Analytical Method Development/ Method Validations/Method Transfers
- Quality Control / In-process / Raw materials /
- Stability studies / Supportive stability studies
- Investigations like OOS/OOE/OOT
- Pharmacopoeia / Health Authority / Regulatory requirements
- GxP / Data Integrity / Quality and Compliance.
- SAP/HPLC/UV

### **Languages :**

- Fluent in English (written and spoken)

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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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