

## Specialist - Quality Operations

Job ID  
REQ-10015984

9月 03, 2024

India

### 摘要

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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部门

Operations

Business Unit

Innovative Medicines

地点

India

站点

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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