

# Specialist Quality Operations

Job ID  
REQ-10015901  
Sep 03, 2024  
India

## Summary

Provide quality support in compliance with cGMP requirements and Novartis Quality Management System. Manage Quality aspects & projects within area of responsibility.

## About the Role

### Major accountabilities:

Have expertise in Supplier Quality management and QMS activities. Drafting of QRA, QAA and AMR documents. Handling Supplier Qualifications and change notification.

Interpret and compile APQR and/ or extracted data from Internal Novartis systems into a pre-defined template and draft conclusion of product quality review.

Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed.

- Provide active support during internal and external audits by collecting and presenting the requested process/ data and reports

- Adherence to the current GxP and compliance policies of Novartis Perform and deliver Quality Operations services in support of product quality compliance and regulatory workflows

- Hold accounts in workflow applications (such as SAP, Dragon, SUBWAY, TEDI etc.) to ensure appropriate execution of service deliverables

- Generate and analyze predefined and ad-hoc reports in various applications (such as AGILE PLM, AQWA etc.) and perform follow-up actions if required

- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements

- Support implementing service quality and process improvement projects, CAPA management within Quality Service Centers

- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket

management tools and other internal systems and processes

### Requirements for the role

- Minimum 6 years of experience in Quality assurance activities in pharmaceutical company.
- GxP knowledge, Basic IT knowledge
- Good communication, presentation and interpersonal skills
- Experience of working closely with the global stakeholders

### Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Gmp Procedures.
- Qa (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

### Languages :

- English.

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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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