

# Analyst – Quality Operations

Job ID  
REQ-10030263  
Nov 22, 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

## About the Role

### Major accountabilities:

- 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, etc.) to ensure appropriate execution of service deliverables
- Support to Stability management eg: Draft reports/assessments of temperature excursion assessments (TEA), transport category assignment (risk assessment (TRA)).
- Support to QC release activities eg: Create, modify and review: Inspection Plans, Inspection Lot Numbers, Certificate Of Analysis, Certificate of Compliance, Specifications etc.
- Support to Testing Monograph management eg: Author testing monograph, Perform impact assessments etc.
- Authoring of risk evaluation reports for Nitrosamines both Step-1 & Step-2. Handling of risk evaluation reports with respect to country specific/local ones. Performing authoring activity in Subway software. Data collection and slides preparation which are required for weekly work stream leads call/Steerco meetings.
- Perform Statistical support, Performance trending and Business support.
- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements
- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket management tools and other internal systems and processes
- Learn & develop understanding to generate insights through data and digital
- Provide active support during internal and external audits.
- Adhere to the current GxP and compliance policies of Novartis

### 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

### Minimum 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

#### **Skills:**

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

#### **Languages :**

- Fluent in English (written and spoken)

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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