

## Specialist-Quality Operation

Job ID  
REQ-10049708

4月 23, 2025

India

### 摘要

-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

Major accountabilities:

- Exposure in handling of customer/market complaints, field alerts, recalls and conducting investigations. Can independently handle meetings/ discussion with business partners/ suppliers.
- Experience in creating Quality assurance agreement and Quality risk assessment for Contract manufacturers / suppliers.
- Understanding on Audits & CAPA management for suppliers.
- Strong understanding on Quality Management System and GxP requirements.

- Provide support in preparation, review and approval of GMP documents including local and global SOPs, WP ' s, Investigation reports, etc., where required.
- Ensure implementation of applicable Novartis QMS requirements in the function.
- Provide support as key user/ Super user for IT tools used for Quality Management System.
- Provide timely and effective communication of any potential compliance gaps/ risks in respective function, the respective SPOCs or Team Lead and facilitate for resolution of identified gaps/ risks.
- Initiate, monitor and fulfill the timely review of APQR documents for all own site and Contract manufacturers.
- Provide quality support to Nitrosamine risk-based evaluation/ Changes, as required. Initiate and implement quality improvement/ simplification projects, wherever possible. Impart trainings on GMP/Data integrity and other relevant trainings, as required.
- Create various periodic performance metrics reports for respective GxP activities and share/ present to Business leaders/ partners.
- Author technical documents (like testing plans, testing monographs, Stability report etc.) and provide data driven technical and analytical insights to improve process understanding, quality and compliance of the product.
- Manage different type of change control like product stewardship/ Administration Stewardship /Asset Stewardship in electronic system like Agile PLM, from Change Initiation to closure as needed.
- Experience in Document Management tools and competency in MS office tools.
- Ensure all time readiness of the activities for internal/ Business partner audits (including data integrity audits), host audits, and manage audit action plans for timely closure of agreed CAPAs.

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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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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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