

# Specialist-Quality Operations

Job ID

REQ-10035539

Jan 05, 2025

Indien

## 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

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Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners.

### Major accountabilities:

#### Common Accountabilities (Applicable to all service teams)

- 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
- Generate and analyse predefined and ad-hoc reports in various applications (like AGILE PLM, AQWA etc.) and perform follow-up actions if required
- Escalate service related GxP and non-GxP issues and ensure timely investigation and compliance with local and global operating procedures
- 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
- Assist the department on any other ad hoc administrative activities as per business requirements.
- Focus on timely completion of all relevant and assigned trainings
- Learn & develop understanding to generate insights through data and digital
- Ensure responsibility and ownership of the assigned tasks
- Comply the accuracy and timeliness of deliverables
- Comply to the applicable Novartis operating procedures as per legal / IT / HR requirement
- Provide active support during internal and external audits by collecting and presenting the requested process data/reports
- Adhere to the current GxP and compliance policies of Novartis.

Key performance indicators:

- Extract data from relevant sources in Novartis tools/ applications.
- Interpret and compile external supplier APQR and/ or extracted data from Internal Novartis systems into a pre-defined template and draft conclusion of product quality review.
- Collect contributory reports for product related evaluations.
- Interact with CMOs and / or manufacturing sites as required.
- Support in updating and maintenance of APQR schedule.
- Perform review of APQR report/ data as applicable to ensure it is complete and correct.
- Complete APQRs within defined timelines.
- Archive the approved APQR as applicable
- Update APQR data in e-compass file followed by interpretation of data to conclude product robustness.
- ☐ **Marketing Authorization Holder (MAH) Review:**
- Support in maintenance of MAH/BRS review schedule
- Coordinate with NCQ SPoCs and/ or manufacturing/ packaging/ testing/ batch releasing sites as required to draft MAH/BRS checklist
- Extract data from relevant sources as applicable and compile MAH/BRS as per the requirements in a predefined format
- Interpretation and consolidation of the data
- Review for accuracy and completeness of compiled data /information
- Submit the drafted MAH/BRS reviews for approval to respective Country quality team
- Archive the approved MAH/BRS review documents

#### **Education Background:**

- M.Pharm/ MBA / Engineering/equivalent from a reputed institute.
- Min 1 yr Experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ Medical device.
- Basic awareness of GxP compliance requirements.

**Why Novartis:** Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

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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.

#### **Accessibility and accommodation**

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Please include the job requisition number in your message

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Division

Operations

Business Unit

Innovative Medicines

Standort

Indien

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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