

# Specialist, Quality Operations

Job ID  
REQ-10028520  
nov 05, 2024  
Inde

## Résumé

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

- Support in updating and maintenance of APQR (Annual Product Quality Review) schedule.
- Perform review of APQR report/ data as applicable to ensure it is complete and correctness.
- Collect contributory reports for product related evaluations.
- Interact with CMOs and / or manufacturing sites as required.
- Complete APQRs within defined timelines.
- Extract data from relevant sources in IT 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.
- Archive the approved APQR as applicable
- Communicate with external suppliers to provide applicable APQR to QOP.
- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed
- Support in maintenance of MAH/BRS review / PQR 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 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 and/or information
- Submit the drafted MAH/BRS reviews for approval to respective Country/ team

- Archive the approved MAH/BRS review documents

**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

Emplacement

Inde

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Qualité

Job Type

Full time

Employment Type

Regular

Shift Work

No

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