

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

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

[Apply to Job](#)

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Job ID
REQ-10028520

Specialist, Quality Operations

[Apply to Job](#)

Source URL: <https://prod1.adacap.com/careers/career-search/job/details/req-10028520-specialist-quality-operations>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist-Quality-Operations_REQ-10028520
5. <mailto:diversityandincl.india@novartis.com>
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist-Quality-Operations_REQ-10028520