

Specialist Quality Operations

Job ID
REQ-10015901
Sep 03, 2024
India

Summary

Provide quality support in compliance with cGMP requirements and Novartis Quality Management System. Manage Quality aspects & projects within area of responsibility.

About the Role

Major accountabilities:

Have expertise in Supplier Quality management and QMS activities. Drafting of QRA, QAA and AMR documents. Handling Supplier Qualifications and change notification.

Interpret and compile APQR and/ or extracted data from Internal Novartis systems into a pre-defined template and draft conclusion of product quality review.

Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed.

- Provide active support during internal and external audits by collecting and presenting the requested process/ data and reports

- Adherence to the current GxP and compliance policies of Novartis 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, TEDI etc.) to ensure appropriate execution of service deliverables

- Generate and analyze predefined and ad-hoc reports in various applications (such as AGILE PLM, AQWA etc.) and perform follow-up actions if required

- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements

- Support implementing service quality and process improvement projects, CAPA management within Quality Service Centers

- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket

management tools and other internal systems and processes

Requirements for the role

- Minimum 6 years of experience in Quality assurance activities in pharmaceutical company.
- 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.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Languages :

- English.

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

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

[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-10015901

Specialist Quality Operations

[Apply to Job](#)

Source URL: <https://prod1.id.novartis.com/id-en/careers/career-search/job/details/req-10015901-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-10015901
5. <mailto:diversityandincl.india@novartis.com>
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist-Quality-Operations_REQ-10015901