

R&D Quality Specialist

Job ID
REQ-10050616

4月 30, 2025

India

摘要

-Manage Quality aspects of clinical programs and projects within area of responsibility. Ensure and support overall GxP conformity and Compliance with the Novartis Quality Management Systems. Identify and execute on OpEx opportunities. Build/manage stakeholder relationships and expectations

About the Role

Major accountabilities:

- Ensures the timely collection, monitoring, and reporting of Quality Key Performance Indicators (KPIs) for management reporting -Assists in Health Authority inspections and internal audits by supplying information and documentation in a timely manner -Support and track the implementation and maintenance of the local Quality system in accordance with the Novartis Quality Manual -Manages processes and systems for all GxP Quality Assurance e.g.

Change control, Training Management, Escalation Management, Risk Management.

- Ensures that processes are conducted in full compliance with the GxP and the Novartis Quality.
- Contributes to an improvement of current processes and/or to an implementation of modified processes.
- Ensures adequate tracking and on time completion of corrective and preventive actions (CAPA), inc escalation of issue related to the closure of CAPA, as appropriate.
- Review quality deliverables to ensure compliance, with health authority requirements and SOPs, including procedural documents, records, third party work, contractors, clinical trial material, components, and gap assessments -Prepare and review GxP documentation; assists in the release of GxP documentation, filing and archiving of GxP documentation Supports Compliance review of projects and inspection readiness and management -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- In accordance with departmental objectives such as support of projects with agreed quality and delivery date -passing of internal and external inspections.
- Maintain sound working relationships with partners and customers -Demonstrated/recognized leader of specific GxP; early external/industry engagement -Basic financial knowledge (e.g., cost management, budget forecast, etc.) -Role Model of Novartis culture, values & behaviors for his/her department

Minimum Requirements:

Work Experience:

- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Agility.
- Audit Management.
- Business Partnering.
- Change Control.
- Continuous Learning.
- Health Authorities.
- Influencing Skills.
- Knowledge Of Capa.
- Qa (Quality Assurance).
- Quality Management.
- Quality Management Systems (Qms).
- Risk Management.
- Root Cause Analysis (Rca).
- Self Awareness.
- Sop (Standard Operating Procedure).

- Technological Expertise.

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>

部门
Development

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

[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-10050616

R&D Quality Specialist

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10050616-rd-quality-specialist>

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/NovartisCareers/job/Hyderabad-Office/R-D-Quality-SpecialistREQ-10050616-1>
5. <mailto:diversityandincl.india@novartis.com>
6. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/R-D-Quality-SpecialistREQ-10050616-1>