

QA Specialist QMS Support

Job ID
REQ-10045026

4月 23, 2025

India

摘要

Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems

About the Role

Location - Hyderabad #LI Hybrid

Key Responsibilities:

- Responsible for managing day to day process of Complaint management activities under complaint hub responsibility.
- Identification, reporting and escalation of critical complaint events followed by building the strong collaboration with NCQ sites to ensure customer service, compliance and efficiencies.
- Responsible for performing reconciliations with stakeholders, e.g. NPS and MedInfo and

responding client with the final outcome of complaints.

- Responsible for preparing Quality trends, evaluate and support team for driving Continuous improvement for processes and product quality performance.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all GxP related activities and that compliance with cGMP is maintained through training and internal audits.
- 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.
- Proficiency in speaking and writing Japanese is a plus and will be considered an added advantage.
- 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)

Commitment to Diversity & Inclusion: :

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

Essential Requirements:

- Quality standards are understood, designed into work activity, and achieved.
- In accordance with departmental objectives such as support of projects with agreed quality and delivery date, passing of internal and external inspections

Desirable Requirements:

Work Experience:

- Functional Breadth.

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>

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity and Inclusion:

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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

Operations

Business Unit

Innovative Medicines

地点

India

站点

Mumbai (Head 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-10045026

QA Specialist QMS Support

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10045026-qa-specialist-qms-support>

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/Mumbai-Head-Office/QA-Specialist-QMS-SupportREQ-10045026>
5. <mailto:diversityandincl.india@novartis.com>
6. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Mumbai-Head-Office/QA-Specialist-QMS-SupportREQ-10045026>