

Quality Manager GCP / PV

Job ID
REQ-10010963
Set 03, 2024
India

Sommario

Quality Manager in area of GCP / PV is a centralized team governing major and critical quality incidents requiring escalation. Quality Manager will drive the assessments of quality issues raised in Research and Development to ensure appropriate escalation, notification, categorization, mitigation, and health authority reporting, as well as consistency in assessment and documentation for all quality incidents. RDQ Incident Manager will be the key liaison between quality and business stakeholders to ensure satisfactory management of quality issues.

About the Role

Quality Manager GCP / PV (Internally role will be called RDQ Incident Manager)

About the Role:

Quality Manager in area of GCP / PV is a centralized team governing major and critical quality incidents requiring escalation. Quality Manager will drive the assessments of quality issues raised in Research and Development to ensure appropriate escalation, notification, categorization, mitigation, and health authority reporting, as well as consistency in assessment and documentation for all quality incidents. RDQ Incident Manager will be the key liaison between quality and business stakeholders to ensure satisfactory management of quality issues.

Key Responsibilities:

- Key point of contact for information on QI process and determination of issue criticality and categorization of issues, next steps, and mitigating actions
- Pharmaceutical experience in area of GCP / PV related to change control, deviation, quality processes and document management.
- Identifying stakeholders for good discussion for decision making
- Prepare pre-reads/presentation and meeting minutes with issue owner
- Develop and maintain templates for presentations, meeting minutes, and HA notifications
- Ensure QI record is raised, maintained, and completed in a timely manner meeting Good Documentation Practices and per processes for incidents in scope of the RDQ Incident Management Team
- Provide oversight of QEM records not in scope with periodic review of records to evaluate adherence to IMT principles to ensure consistent approach
- As a process SME, drive timelines for process steps
- Lead and manage Health Authority reporting as needed to ensure reporting is completed in a compliant manner and that Novartis assures adequate responses to Health Authority inquiries
- Support completion of weekly escalation updates and monthly global reports on status of incidents (i.e.

CEO report, DRC report, Global Quality Update)

- Develop and maintain network of key stakeholders in R&D to ensure appropriate input and support of quality issues

Essential Requirements:

- 8+ years industry experience specifically in clinical operations and clinical site management with a strong understanding of clinical research international standards and regulatory requirements from Health Authorities. Audits and inspections experience highly desirable.
- Strong experience in area of GCP / PV related to change control, deviation, quality processes and document management.
- Organizational and analytical skills associated with a proficiency in quality management and continuous improvement.
- Critical thinking ability and risk management and risk- based knowledge and approach.
- Ability in partnering with a proactive and solution- oriented approach.
- Strong skills to facilitate/optimize contribution of team members as individuals and members of a cohesive team.
- Ability to work effectively in a matrix cross-functional environment.
- Strong capacity for working independently with minimal supervision.
- Ability to make & communicate difficult decisions, associated with strong written and verbal communication skills.
- Self-awareness, willingness to further develop own strengths and explore opportunities for improvement.

Desirable Requirements:

- Bachelor/Technical degree in Life Sciences or related fields. Advanced degree and/or MBA an advantage

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>

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>

Development
Business Unit
Innovative Medicines
Posizione
India
Sito
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-10010963

Quality Manager GCP / PV

[Apply to Job](#)

Source URL: <https://prod1.adacap.com/careers/career-search/job/details/req-10010963-quality-manager-gcp-pv>

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/RDQ-Incident-Manager_REQ-10010963
5. <mailto:diversityandincl.india@novartis.com>
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/RDQ-Incident-Manager_REQ-10010963