

Quality Manager GCP / PV

Job ID
REQ-10010963
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Summary

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)

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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

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