



Example of Clinical Quality Manager Job Description

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Our innovative and growing company is looking to fill the role of clinical quality manager. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

Responsibilities for clinical quality manager

- Conduct quality reviews or audits of clinical study documents, which include investigator brochures, clinical protocols/amendments, clinical study reports, case report forms and informed consents forms
- Conduct internal audits to ensure stakeholder system compliance with existing policies and procedures, and GCP requirements, standards and guidelines
- Provide expert CQA advice to stakeholders (e.g., Clinical Operations, Data Management, Pharmacovigilance,) based on analysis and interpretation of GCP regulations
- Conduct targeted training of investigators/site staff when required
- Report GCP related deficiencies to QA management, plans for corrective and/or preventive actions (CAPA)
- Assist clinical study teams in the development of CAPAs
- Assist with regulatory agency inspections
- Serves as a lead/coordinator of investigations and corrective and preventive action (CAPA) recommendations related to manufactured products
- Understand the phases, processes and techniques used to execute a Quality Assurance Plan
- Provide Administrative Support, such as maintain audit logs, update checklists, templates, , as required

Qualifications for clinical quality manager

- Position requires a highly diplomatic, tactful and detail-oriented individual with exceptional critical reasoning skills
- Ability to use expertise and skills to contribute to the development of company objectives and principles, and to achieve goals in creative and effective ways
- Ability to deal with ambiguity, and develop creative and pragmatic solutions to GCP compliance risk areas
- Ideal candidate may work remotely but will be expected to travel 30-40% of the time
- RQA-GCP certification is a plus
- Bachelor's degree in the Life Sciences and a minimum 3 years of experience in supporting clinical operations for the Senior Associate level