Example of Quality Compliance Specialist Job Description

Our innovative and growing company is looking to fill the role of quality compliance specialist. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

Responsibilities for quality compliance specialist

- Focused QA Representative on review/approval of Final Reports, CoA's, Non-Conforming Events (NCEs), Investigations (OOS), and CAPA's
- Maintain awareness of evolving industry and regulatory trends/regulations
- Lead & Coordinate with Procurement and impacted Site Quality leads on critical audit findings and or audit refusals
- Ensure that plan, policies and procedures comply with regulatory, investor and agency requirements and are incorporated into daily operating procedures
- Be responsible for documentation quality review/approval or audits, documentation maintenance and archival, quality inspections of product, and participating on internal assessments
- Assist in compiling documentation to release R&D studies and will provide guidance on applicable Regulations (FDA, ICH, EU, and others) pertaining to business partners
- Provide GMP documentation review and approval of batch records (Manufacturing, Packaging, and Labeling) and related documents, including Lab, Pilot, and Trial scale batches
- Participate on R&D project teams as the Quality representative
- Work with these groups relative to GMP issues, project plans, due dates, and problem identification and resolution along with assisting in compiling documentation to release R&D studies
- Provide Quality guidance on GMP regulatory requirements (including 21CFR

Qualifications for quality compliance specialist

- Minimum of 5 years of experience in the pharmaceutical industry as a quality auditor (CQA), Manufacturing Operations, QC, and/or other cGMP areas
- Knowledge and understanding of the current Good Manufacturing Practices (GMP) and International Conference on Harmonization (ICH) guidelines
- Basic understanding of Biopharmaceutical Manufacturing, Analytical Chemistry and Chemical Manufacturing processes
- Knowledge and understanding of practical quality assurance in the manufacturing environment, laboratory controls and safety
- Ability to read and understand procedures and other controlled documents
- Good written and verbal communication skills, interpersonal skills, and technical writing skills