



Example of Quality Compliance Specialist Job Description

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Our innovative and growing company is searching for experienced candidates for the position of quality compliance specialist. 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 quality compliance specialist

- Evaluate the appropriateness and effectiveness of complex corrective actions
- Assist in generating metrics for overall auditing system and identify continuous improvement opportunities
- Develop audit process findings, and may have input to improve process flow for compliance
- Provide training, guidance, and coaching to team members
- Responsible for the handling of change requests from the departments, such as Master Batch Records (MBRs), Specifications (SPECs), General Changes (GENs)
- Develop, check or revise pharmaceutical Quality Agreements
- Develop and execute inspection/audit prep plans and manage the inspection readiness activities (maintain key contact list, prep/strategy sessions, inspection readiness training)
- Working with Engineering/R&D/Product Management and external OEM suppliers, develop design verification and validation (V&V) strategies to support high quality, compliant and best speed-to-market product launches
- Review and approve claim support data and V&V protocols/reports
- Review and approve user requirements/product specifications ensuring input from Marketing/Product Management

- Minimum 3 years' experience in Quality, Regulatory, Technical, or Manufacturing Operations in the area of regulatory inspections
- Auditor certification or equivalent preferred
- Good knowledge and understanding of diverse and applicable regulations and standards relevant to medical devices (e.g., 21 CFR Part 11/50/54/56/801/803/806/807/820/812/814/821/822, ISO 14155)
- Analyze and understand technical and scientific documents, and governing regulatory research information and data
- Possess professional level knowledge of U.S. export regulations including Customs, BIS/ Export Administration Regulations, OFAC and Federal Trade Regulations (Census/FTR)
- 7+ years professional air quality compliance experience