Example of Compliance / Quality Specialist Job Description

Our company is looking to fill the role of compliance / quality 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 compliance / quality specialist

- Provide independent assessment and advice during design review meetings
- Provide expertise as a subject matter expert (SME) for Design Control as per ISO13485, FDA QSR Part 820 and other international regulatory requirements
- Provide expertise as a SME for Risk Management as per ISO14971 and other international regulatory requirements
- Provide expertise as SME for global certification of electro-mechanical products including CB reports, CSA
- Coordinate with Engineering/R&D team members to ensure that electrical safety/EMC testing is performed as required to IEC 61010
- Review and approve design transfer plans and activities to ensure effective design transfer from Engineering/R&D to manufacturing & Service
- Participate in new product post launch support teams and prepare post market review data/metrics for management/stage gate review
- Support the preparation of CE Technical Files to demonstrate compliance with In-vitro Diagnostic Device, Medical Device, Low Voltage & Machinery Directives
- Evaluate and approve proposed product design changes (member of 'Change Review Board') and give direction on testing/verification/validation requirements needed for change approval
- QWS

Qualifications for compliance / quality specialist

- Advanced Career Experience in a GMP environment and in Quality Assurance or similar discipline
- The position will be located in Skillman, NJ and may require up to 10% travel.R&D
- B.S., B.A., or M.S
- Knowledge of FDA 806 & 803, MEDDEV Vigilance, QMS requirements (QSR820 and ISO 13485 / ISO 9001)
- Associate's degree required, Bachelor's degree in Science, Healthcare Administration, or Management strongly preferred