Quality Systems Engineer II

Purpose Statement

Provide quality assurance oversight for the Operations Group to ensure compliance with all applicable regulations including documentation reviews, discrepancy system management, audit support, technical, projects, and documentation.

Key Responsibilities

- Facilitate development and maintenance of the quality management system according to ISO, MDD and FDA requirements.
- Maintain the CAPA system to ensure proper notification, impact assessment, root cause analysis, investigations and effectiveness verifications to ensure all requirements are met.
- Provide system administration duties and technical interface with consultants to support and maintain the Manufacturing Pro database, including software changes and re-validation activities.
- Perform audits/assessments internally and of suppliers for compliance to quality system and regulatory requirements. Support internal and external audits as well as follow through on audit responses.
- Maintain the PIR process, including compliance to procedures, timelines, and reporting to BSC
- Lead special projects that require Quality Assurance expertise including improvements to quality systems.
- Perform trending of data and quality systems as relates to annual reporting, management metrics and other trending, as required.

Quality System Requirements

In all actions, demonstrates a primary commitment to patient safety and product quality by maintaining compliance to the Quality Policy and all other documented quality processes and procedures.

Basic Qualifications

Bachelor's and 3-5 years of relevant industry experience; including experience in the medical device industry

Preferred Qualifications

•ASQ (or similar) certification preferred

•Excellent interpersonal skills

•Strong presentation skills and MS Office skills

•Experience with major systems (e.g. eCAPA, PDM, CRD, SAP, VIP, Clarizen) desirable

•Strong analytical and investigation skills

•Leadership potential