

JOB DESCRIPTION

Position Title: Senior Quality Engineer, New Product Development
Reports to: Director of Quality
Department: Quality
FLSA Status: Exempt

PURPOSE OF JOB: Responsible for supporting the quality needs of new product development and the successful completion of individual projects. Must establish and maintain quality assurance standards that adhere to the QSR and ISO regulations.

MAJOR DUTIES AND RESPONSIBILITIES:

- Support quality-related activities from product development, production/process controls through post-market services
- May develop and update SOPs that support the QMS
- Ensure that all company employees follow written SOPs and process specifications.
- Lead validation activities to support commercial launch of new products
- Support the design team by leading the quality deliverable activities for new product development
- Support design team to create and update Design Description Document for new products
- Perform design and process FMEAs throughout all design phases of the project
- Create and maintain Quality Plans for the project teams
- Evaluate test methods and support the test method development activities
- Protocol and report generation for gage R&R testing
- Determine sampling plans and create testing protocols based on statistical rationale
- Statistical data analysis and interpretation to support investigations and specification setting activities
- Identify and assist with implementation of preventive and corrective actions via CAPAs, audits, NCMRs, and complaint handling systems.
- Participate in inspections for FDA, FDB, ISO, MDD, and other regulatory agencies
- Periodically conduct internal audits and inspect facility to ensure QSR/GMP compliance.
- Support company goals and objectives, policies and procedures, QSR, and FDA regulations.
- May perform external audits on key suppliers/vendors.

EDUCATION /EXPERIENCE REQUIREMENTS:

Bachelor's degree in Engineering/Life Sciences and a minimum of 10 years medical device experience. Experience with quality system elements pertaining to combination products (drug/device) and cGMP familiarity is strongly preferred.

OTHER QUALIFICATIONS: Strong written and verbal communication skills and attention to detail is a must. Must have strong technical writing skills. Will be expected to work independently and have the ability to mentor junior quality associates.

This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.