

JOB DESCRIPTION

Job Title: Quality Engineer
Department: Quality
Reports To: Quality Systems Manager
FLSA: Exempt
Survey Job Code: 6311 – 6316
Survey Job Title: Quality Engineers

Summary:

Provides support in the development and maintenance of company's Quality Systems. Plans and implements Quality System programs designed to ensure continuous production of products consistent with established standards by performing the following duties:

Essential Duties and Responsibilities:

- Responsible for managing the internal audit and corrective action (CAPA) systems.
- Responsible for maintaining the risk management system, reviewing risk control actions for completeness, feasibility and adequacy. Track mitigation efforts to reduce medium and high risks to acceptable levels.
- Responsible for reporting and trending of CAPA, Internal Audits and Risk Management.
- Conducts FMEA review for complaints/customer experience reports.
- Investigate, audit, analyze, and propose improvements in the Quality Management System.
- Assist during FDA inspections, Notified Body, customer audits and other third party audits.
- Responsible for reporting and trending of CAPA, Internal Audits and Risk Management.
- Assist and perform training to procedural and quality system changes.
- Performs other duties as assigned.

Education, Training, Skills and Experience Requirements:

- Minimum of 7-10 years quality engineering experience in an FDA regulated industry.
- Demonstrated an understanding of and ability to interpret regulations and guidelines governing medical devices including QSR's, ISO 13485, CMDR and MDD.
- ASQ CQE and CQA preferred.
- Comprehensive understanding of auditing principles and ability to perform as a lead auditor.
- Bachelor's degree in a scientific discipline is required.
- Demonstrated understanding and experience in applying quality engineering concepts such as risk assessment, pFMEA and dFMEA.
- High level of competence in Quality including formal root cause analysis (e.g. DMAIC, etc) and managing deployment of corrective and preventive actions.
- Strong communication and organization skills required.
- Good judgment skills within generally defined practices and policies in selecting methods and techniques for obtaining solutions.
- Flexibility to handle multiple tasks and meet timelines. Normally receives minimal instructions on routine work, general instructions on new assignments.

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee is regularly required to stand; walk, and sit for extended periods of time.

Print Name

Employee Signature

Date