

Quality Assurance Audit Lead

Summary:

Based in our Quakertown, PA facility, the Quality Assurance Audit Lead serves as QA representative for customer and regulatory audits, manages Auditing systems (Internal and External), coordinates and implements various activities for the compliant and effective management of the Quality Management System (QMS) in support of ISO 13485, internal and customer compliance.

Responsibilities:

- Host, prepare and coordinate Customer and Regulatory audits. Serve as QA representative during the audit and defends Company systems and practices.
- Coordinate, implement and manage activities related to the successful overall management of the Supplier Audit Systems and conduct Supplier Audits as required.
- Coordinate, implement and support activities related to the successful overall management of the Internal Audit Systems. Responsible for scheduling, planning, conducting, communicating and reporting on internal audit results. As part of audit execution, perform timely and adequate follow up on previous audit nonconformities.
- Coordinate, implement and support activities related to the successful overall management of the following quality systems: Change Control, Supplier Quality, Corrective Actions and Preventative Actions (CAPA) Events/Nonconformances, and customer complaints.
- Assist in the design, development, implementation and maintenance of quality systems, projects and initiatives that support departmental and company objectives while ensuring compliance to applicable standards and requirements.
- Support investigation activities regarding Out of Specification (OOS) failures, CAPA Events and customer complaints.
- Support additional quality systems and functional areas as needed and/or assigned including, but not limited to Preventive/Unscheduled Maintenance, Calibration, Validation, Training, and Regulatory Assurance.
- Act as a Quality ambassador for the company to promote Quality culture
- Participate in or lead special company and corporate initiatives and projects as needed and assigned.
- Follow established safety requirements and adheres to Fenner Framework HSE Management System.
- Performs other job-related responsibilities as assigned.

Qualifications:

- Knowledge of applicable regulatory standards, specifically ISO 13485, ISO 9001 and 21 CFR Part 820.
- Detail-oriented, with high attention to detail and ability to work on and coordinate multiple projects/assignments.
- Strong written and verbal communication skills.
- Demonstrated ability to organize and manage small to medium-sized projects and effectively participate in cross-functional teams.
- Intermediate to advanced knowledge of MS Office Suite.
- Strong problem solving and organizational skills.
- Knowledge of regulated environment (e.g., ISO 9001, ISO 13485, 21 CFR Part 820).
- Lead Auditor certification is preferred
- 3 to 5 years experience in regulated industry in Quality Assurance or Operations

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