Quality Assurance Specialist

FLSA Status
Exempt

Job Summary
The Quality Assurance Specialist works directly with the Quality Assurance Manager and supports and assesses operational needs and activities to successfully achieve quality goals and metrics across multiple quality functions.

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- Assist in the maintenance and tracking of all Quality related documentation including, but not limited to: SOPs, Protocols, NOEs, Investigations, CAPAs, Planned Deviations, Change Controls, etc.
- Maintains all investigation and CAPA related documentation as assigned while ensuring adherence to, and compliance with, established company quality policies, practices, SOPs and cGMPs.
- Assists in investigations, root cause analysis, Corrective and Preventive Action (CAPA) activities in accordance with the company's Quality System.
- Tracks and trends appropriate metrics for open NOEs, Investigations, CAPAs, planned deviations, etc.
- Reports monthly metrics pertaining to NOEs, investigations, and CAPAs to Quality department management and other appropriate company personnel.
- Actively participate in the review and approval of batch record documentation to support quality release of drug product in a timely manner.
- Perform risk assessment to determine safety and efficacy of products.
- Assist in change control management program and document archival.
- Maintain compliance with company policies, regulatory requirements, quality specifications, safety standards, and sanitation practices.
- Perform routine audits of processes and establish gap analysis.
- Perform quality review of documentation and processes.
- Assists with SOP revision and participates in inspections, as needed.
- Assists in other areas of QA and may cross train across department, as needed.

Required Education and Experience

- Minimum of 6 years of experience in pharmaceutical manufacturing, quality assurance, and/or FDA regulated industry without degree.
- Minimum of 3 years of experience in pharmaceutical manufacturing, quality assurance, and/or FDA regulated industry, with degree.
- Bachelor's Degree in Biological Science, Chemistry, Biomedical Engineering, or relevant field, preferred.
- Familiar with GxP, FDA, ICH, and OSHA requirements.
- Familiar with Microsoft Office applications (Word, Excel, etc.).
- Must be capable of wearing all protective wear as required. This includes, but not limited to, mask, gloves, gown, hairnet, safety goggles, etc.
- Must have strong organizational skills and exceptional attention to detail.
- Must exhibit punctuality and low absenteeism.
- Able to work independently and as part of a team.
- Able to sit, stand, squat, kneel, reach and walk for prolonged periods of time.
- May need to lift up to twenty-five (25) pounds on occasion.

Competencies

- Communication Proficiency
- Problem Solving/Analysis
- Quality
- Results Driven
- Technical Capacity
- Thoroughness

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

This job operates primarily in a controlled laboratory environment. This position requires the use of standard office equipment, and frequent standing and walking.

Language Skills

Must be able to read, write, speak and understand English fluently and have the ability to read and interpret documents such as operating and maintenance instructions and procedure manuals.

Mathematical Skills

Uses addition, subtraction, multiplication and the division of numbers including decimals and fractions when checking of reports, forms, records and comparable data where interpretation is required involving basic skills knowledge.

Reasoning Ability

Must have the ability to solve practical problems and deal with a variety of concrete variables in situations where substantial standardization exists. Must be able to interpret instructions furnished in written, oral, and diagram or schedule form.

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.

- Able to sit and/or stand 8-10 hours or more per day as needed.
- May need to lift up to twenty-five (25) pounds on occasion.

Position Type and Expected Hours of Work

This is a full-time position. Because of the nature of the business, work schedules may vary at times.

Travel

No travel is expected for this position.

Disclaimer

The above job description is intended to describe the general nature and level of work being performed by employees assigned to this job. It is not designed to capture or illustrate a comprehensive list of all responsibilities, duties, and skills required of employees assigned to this job.

AAP/EEO Statement

Stokes Healthcare is an Equal Employment Opportunity and Affirmative Action Employer.