Quality Assurance Manager

Full Time
Mt. Laurel, NJ,

Job Title
Quality Assurance Manager

FLSA Status
Exempt

Job Summary
The Quality Assurance Manager is a leadership role within a 503B Outsourcing Facility responsible for ensuring FDA compliance is met in accordance with 21 CFR Part 11, 210, and 211. This includes managing quality systems, quality procedures relating to raw materials and finished product, product stability, managing day-to-day operations, and finished product release. The Quality Assurance Manager reports directly to the Director of Quality.

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

- Ensure compliance with FDA regulatory guidance and company policies
- Assist in regulatory audits with the FDA and applicable regulatory bodies
- Lead stability protocol development, coordinates study execution (i.e., internal and external testing), and completes stability protocol final report
- Lead investigations for deviations/discrepancies for laboratory and manufacturing departments
- Perform root cause analysis using industry standards, such as FMEA, 5Whys and Fishbone diagrams
- Perform trend analysis of critical process parameters and evaluate KPIs to determine procedure effectiveness
- Assist in the develop and execution of relevant corrective and preventative action
- Perform risk assessment to determine safety and efficacy of product
- Lead in the development and implementation of new and existing processes:
    - Master and Batch production control records
    - Receipt and release process of incoming materials for manufacturing and QC testing
    - Product Stability
    - Labeling issuance for materials and drug products
    - Laboratory Information Management System
- Oversee the review and approval of batch record documentation to support quality release of drug product in a timely manner
- Lead in development and maintaining of quality inspection process for sterile and non-sterile drug products (e.g., blister packaged tablets)
- Lead in the execution of annual products reviews
- Oversee change control management program and documentation archival
- Work closely with QA/QC staff to evaluate all customer issues, perform root cause analysis and respond appropriately
- Oversee performance of routine audits of processes and perform gap analysis

Required Education and Experience

- Minimum of 10 years of experience in pharmaceutical manufacturing or compounding pharmacy quality assurance, without degree

- Minimum of 8 years of experience in pharmaceutical manufacturing or compounding pharmacy quality assurance, with degree
- 4+ years' experience in a supervisory role, preferred
- Bachelor's Degree in Biological Science, Chemistry, Biomedical Engineering, or relevant field, preferred
- Excellent communication and technical writing abilities
- Extensive knowledge with GxP, FDA, ICH, and OSHA requirements
- Proficient 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

Competencies

- Communication Proficiency
- Problem Solving/Analysis
- Quality Oriented
- Results Driven
- Technical Capacity
- Thoroughness
- Troubleshooting
- Time Management
- Employee Engagement
- Work Independently

Supervisory Responsibility

This position has supervisory responsibilities of the Quality Assurance Department.

Work Environment

This job operates primarily in the Quality and Manufacturing Areas. This position requires the use of standard office equipment, and frequent standing and walking.

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
- Able to squat, kneel, reach and walk for prolonged periods of time
- 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.