Quality Control Analyst - Environmental Monitoring

Full Time
Mt. Laurel, NJ
Requisition ID: 1353

FLSA Status
Non-exempt

Job Summary
This position requires an individual who can work collaboratively with production personnel to optimize quality aspects of operations.

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

- Learn aseptic gowning and technique within a cleanroom environment
- Learn and apply GxP (GMP, GDP, GLP) to operations
- Perform viable/non-viable environmental monitoring and read/review microbial samples
- Assist in the media-fill process validations and inspection of filled units
- Perform document review of operation activities such as cleaning record, line clearance forms, and inventory/equipment checklist
- Document non-compliance and work with supervisor/lead if further investigation is needed
- Review production batch records and associated data for product release; determine if records are within cGMP regulations; review data obtained for compliance specifications and report abnormalities
- Perform audits on aseptic technique and operation documentation
- Ensure completeness and accuracy of information contained in all documents, document files, databases, and documentation systems
- Ensure timely assessment and closure of Change Controls
- Assist with equipment calibration program and maintenance record files
- Identify and assess quality risk in activities and processes according to regulatory guidelines and Standard Operating Procedures
- Assist in the training of new employees and other technical personnel

Required Education and Experience

- Bachelor's degree in biology, microbiology, or other related field, **or** 1 year relevant experience in cGMP environment
- Must be capable of wearing all protective gear (gown, hair bonnet, mask, beard cover, gloves, goggles)
- Must be able to follow gowning/garbing procedures (cannot wear makeup, must remove jewelry before sterile compounding)
- Must learn and understand 21 CFR Part 210 and Part 211, along with other relevant cGMP regulations
- Must be capable of working with small, delicate pieces of machinery to complete appropriate dosage forms in a timely manner
- Must possess strong verbal, written, and oral communication skills
- Must be able to work independently and with a team
- Must possess problem-solving skills
- Ability to recognize priorities and take action; make productive use of time

- Must exhibit punctuality and low absenteeism
- 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

Competencies
- Communication
- Organizational Skills
- Problem Solving/Analysis
- Results Driven
- Technical Capacity
- Thoroughness

Supervisory Responsibility
This position has no supervisory responsibilities.

Work Environment
This job operates primarily in an office environment. This position requires the use of standard office equipment, and frequent standing and walking.

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.
- May need to lift up to twenty-five (25) pounds on occasion
- This position is moderately active and requires standing and walking for a majority of the shift.

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.