

Quality Control Analyst I – Manufacturing

Job Summary

Quality Control Analysts are responsible for ensuring the quality of materials and that finished drug products are manufactured to meet current Good Manufacturing Practice (cGMP) and Epicur Pharma standards.

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

- Perform quality inspection on incoming materials intended to be used in the manufacturing of drug products.
- Perform in-process quality checks and inspections for finished drug products to ensure standards are met.
- Assist in documenting and maintaining material and product samples (i.e., retains, stability, finished products, etc.)
- Perform logbook reviews for accuracy and good documentation practice.
- Document inspection and testing results by completing QC reports and logs
- Participate in the execution/verification of corrective and preventative action (CAPA) and change controls.
- Complete batch record documentation for quality release of finished product.

Required Education and Experience

- High school diploma or general education degree (GED).
- Familiar with cGMP and 21 CFR Part 210 & 211 preferred, but not required.
- 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 entering manufacturing area).
- Must possess strong verbal, written, and oral communication skills.
- Must be able to work independently and with a team.
- Able 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

- Results Driven
- Technical Capacity
- Thoroughness

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

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

FLSA Status

Non-exempt

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.