

QC Document Reviewer



Department: Quality Control
Reports to: Supervisor

FLSA Status: Non-Exempt
Location: 110 Terry Drive

BASIC FUNCTION: The QC Data Review Specialist will be responsible for GMP review and comment on laboratory raw data, procedures and reports to ensure methods, protocols and other procedures were properly followed, results are analytically accurate and correct, and that all documentation meets GMP standards.

JOB RESPONSIBILITIES:

- Daily activities include review of documentation generated during method development, method validation, stability testing, routine testing and other analyses.
- The individual will interface with their supervisor, the analytical groups and QA on a daily basis.
- Review documentation, results and reports from raw material and finished product analysis for accuracy and completeness.
- Provide feedback from reviews to analysts and supervisor and ensure necessary action are taken to correct or prevent error.
- Review data using a systematic approach to ensure compliance with procedures and specifications.
- Review and audit projects as required. Perform other duties assigned by supervisor as needed.
- A KRA is a Key Result Area that is aligned with the department's objectives. It is a core responsibility for the candidate that is linked to a specific measure of achievement called a KPI (Key Performance Indicator). KPI measurements will be used to judge the candidates performance during their annual review, as a measure of their ability to perform their core duties optimally.

ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS

- Bachelor's degree in Chemistry or a related field
- GMP laboratory experience: minimum 1 year, Experience with instrumental techniques a plus.
- Years of Experience (mention specific core function requirements as well): One to two years experience in a GMP lab using HPLC, GC, and/or related analytical techniques. QC data review experience a plus
- Preferred Industry/Former Companies: Pharmaceutical or a related field

PHYSICAL DEMANDS: While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

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The job demands here are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. This job description is not intended and should not be an exhaustive list of all principal job elements essential for recruitment and selection, for making fair job evaluations and for establishing performance standards. The percentage of time spent performing the various job duties is not absolute. The incumbent, who has the right to amend, modify, or terminate this job in part or in whole. This document is not a contract for employment.