

Job Description

Job Title:

Quality Control Analyst II

Job Summary:

The Quality Control Analyst II performs testing and solution preparations, performs equipment & instrumental calibrations and maintenance, communicates between departments when reporting results, and executes complex protocols as assigned by management. The analyst is also responsible for assisting in writing protocols & reports, as well as sampling raw material, finished goods, stability samples and additional samples as assigned.

Essential Duties and Responsibilities:

- ✓ Performs all test methods without supervision
- ✓ Prepares all solutions needed for testing
- ✓ Performs testing on stabilities
- ✓ Samples raw material, finished goods, stability samples and additional samples as assigned.
- ✓ Performs instrument & equipment calibrations/performance checks
- ✓ Performs testing on raw material, in-process, & finished good samples
- ✓ Documents all data in corresponding laboratory notebook
- ✓ Disposes of all chemicals safely
- ✓ Performs required testing pertaining to customer complaints, discrepancies, & laboratory investigations.
- ✓ Reports necessary results to production supervisors, in a timely manner
- ✓ Reviews laboratory SOPs
- ✓ Reviews and approves laboratory notebooks
- ✓ Assists in the performance of qualifications and validations of instruments and test methods
- ✓ Performs impurity, supplier approval, and research testing
- ✓ Performs tests using more complex instrumentation
- ✓ Troubleshoots and maintains basic instruments
- ✓ Executes basic & complex protocols, as assigned by management
- ✓ Assists in writing protocols and reports
- ✓ Ensures that the required samples are sent for outside testing
- ✓ Performs daily laboratory maintenance
- ✓ Trains new employees basic laboratory skills and functions
- ✓ Other duties may be assigned as deemed appropriate by management

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- ✓ Bachelor Degree in Life Science related discipline an educational equivalent, one year experience as a QC Analyst I or approved and documented equivalent experience. Has complete understanding of GLP, cGMP and Q7A

- ✓ Follows and complies with majority of methods found in FCC, ACS, USP/NF, EP/BP, and JP compendia's. This includes all general chapters and monographs associated with reagent, raw material, and finished good products at BioSpectra

Physical Requirements:

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. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is frequently required to stand or walk for long periods of time; sit; use fingers to make small equipment adjustments; reach with hands and arms; and talk or hear. The employee must regularly lift and/or move up to 10 pounds and occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, distance vision, ability to adjust focus, ability to distinguish color change, and the ability to use a computer for extended periods of time.

Working Conditions:

The noise level in the work environment is usually moderate.

Work Hours:

The Quality Control Analyst II will be required to work up to 40 hours per week. This is an hourly position requiring the Analyst to record the working hours on a time card using the available time clock.

All BioSpectra job functions require the ability and willingness to work from the Stroudsburg, PA or Bangor, PA facility.