BIOSPECTRA

100 Majestic Way, Bangor, PA 18013

Job Description

Job Title:

Cleaning Validation Specialist

Job Summary:

The Cleaning Validation Specialist is responsible for all aspects of Process Cleaning Development and Process Cleaning Validation from start to finish, including establishing, managing, and maintaining a scientifically sound cleaning validation program. The Cleaning Validation Specialist is responsible for the Bangor and Stroudsburg sites.

Essential Duties and Responsibilities:

- ✓ Write, review and/or revise Process Cleaning Validation Master Plans.
- ✓ Lead and perform risk assessments for determination of most critical cleaning conditions and acceptance criteria.
- ✓ Write, review and execute cleaning related method validations including specific and non-specific analytical methods, extraction studies, and recovery studies.
- ✓ Write, review and execute cleaning development protocols including lab scale coupon studies, full scale spray coverage testing, and full scale cleaning recipe and procedure development.
- ✓ Responsible for development final reports summarizing development data and risk assessments for determination of cleaning matrix, family approach, and critical cleaning parameters for validation.
- ✓ Write, review and execute cleaning validation protocols for product manufacturing and support processes, including analysis and review of test data results.
- ✓ Responsible for summarizing results and conclusions when writing final reports. Ensure final reports and study data is reviewed and approved in a timely manner after execution is completed.
- ✓ Responsible for developing and managing the cleaning monitoring program including discrepancy investigations and periodic reports.
- ✓ Perform sampling for cleaning studies including collection of rinse water sampling and surface swab sampling and the submission of samples to QC lab for testing.
- ✓ Coordinate and schedule cleaning development, validation and, continuous monitoring/verification activities with appropriate departments.
- ✓ Lead the investigation of deviations encountered during the execution of validation and/or continuous monitoring/verification activities and provide documentation to support the findings of the investigation.
- ✓ Responsible for overall supervision and oversight during execution of validation activities.
- ✓ Write and provide training on SOPs relevant to cleaning validation procedures.
- ✓ Evaluate cleaning procedures and revise with process improvements as necessary.
- ✓ Train other personnel on rinse sampling and surface swab sampling.
- ✓ Review technical and quality system documents such as SOPs, Change Control and Deviation Reports, Batch Production Records, as they relate to validation and regulatory compliance issues.
- ✓ Knowledgeable of current FDA guidelines and industry standards pertaining to cleaning validation.
- ✓ Other duties may be assigned as deemed appropriate by the Director of QA.

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.

- ✓ Four year degree in Science, Engineering or related field
- ✓ Five years of experience in cleaning validation with knowledge of current best practices
- ✓ Has knowledge and understanding of cGMP & ICH Q7
- ✓ Have excellent analytical skills with systematic approaches to problem solving
- ✓ Must have experience in the principles and approaches of product/equipment cleaning validation
- ✓ Ability to communicate effectively at all levels in verbal and written form, including technical/business writing
- ✓ Organized, Thorough, Neat
- ✓ Confidentiality

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 Cleaning Validation Specialist will be required to work up to 40 hours per week and is a salaried position. Extenuating circumstances may require additional time for certain periods. It is widely assumed that displacement of hours and/or days will occur on recurring and non-patterned basis.

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