Chemistry Supervisor

Location: Mount Laurel, NJ US

FLSA: Exempt

Job Summary

The Chemistry Supervisor is responsible for managing the team responsible for analytical testing of products and components in a CGMP facility. Such testing may include, but not limited to, HPLC/UPLC analysis, dissolution/disintegration, compendial testing, and coordination with third party testing. Other duties include development, validation, implementation, and monitoring of all processes relating to analytical testing.

The role is intended to provide direction for the chemistry group by scheduling/prioritizing routine testing and projects to optimize efficiencies. This position will also require effective interaction with other departments within the company and with external parties.

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

- Manage the Chemistry team: staff support, coaching, training and recruitment. Ensure planning in place for new hire training and career development for staff
- Performs analytical testing on the following:
    - Raw Materials
    - In-Process Testing
    - Finished Product
    - Stability Samples
    - Retain Samples
- Ensures equipment documentation is maintain and calibrations/qualifications are current for usage
- Perform method development and generate protocols for method validation
- Assist in the development and generation of stability protocols in accordance with ICH and FDA guidelines
- Ensure data is accurate and approved to support product release, annual product reviews, stability program, and investigative reporting
- Hands on with different mode of chromatography and spectrometry
- Develop user requirement specifications and implementation plan for new equipment within a cGMP facility
- Develop and revise SOPs, Protocols, Specifications, and Data Reports
- Participate in investigations and CAPA development
- Generate schedule and assign activities, for the chemistry team, for routine testing and validation projects
- Assigns tasks to maintain chemistry lab is organized and logbooks are accurate
- Documents laboratory deviations and performs investigation of discrepancies
- Spearheading/supporting process improvements and efficiencies on your team and in the Lab
- Tracking and reporting KPIs, identifying gaps in expectations and solutions for improvements

Regulatory Responsibilities include the following. Other duties may be assigned.

- Understand and develop knowledge of FDA regulatory expectations for departmental development
- Ensure testing is performed accurately and in accordance with GxP, USP, and company standards
- Participate in regulatory audits, when applicable

Required Education and Experience

- Minimum 8 years' experience in analytical testing within the pharmaceutical industry or related field. PhD *or* MS in Analytical Chemistry preferred
- Minimum 3 years supervisory experience

- Understanding of analytical chemistry test methods and instruments (i.e., UPLC-MS, Raman Spectroscopy, GC, IR, etc.)
- Understanding of laboratory safety requirements
- Ability to work independently and troubleshoot challenges
- 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
- Recognize priorities and take action; make productive use of time
- Must exhibit punctuality and low absenteeism

Competencies

- Communication Proficiency
- Leadership Skills
- Problem Solving/Analysis
- Quality Driven
- Results Driven
- Technical Capacity
- Thoroughness

Supervisory Responsibility

This position has supervisory responsibilities.

Work Environment

This job operates primarily in a controlled laboratory environment operating under GxP. 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.

- Ability to lift 25-50 pounds (i.e., equipment and materials relating to the lab)
- Able to sit and/or stand 8-10 hours or more per day as needed

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.