

Chemistry Analyst III

Mount Laurel, NJ, US

Job Title

Chemistry Analyst III

Job Summary

Supports cGMP analytical chemistry analysis associated with processes related to routine testing, stability testing and method transfer.

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

- Training Lead
- Independently performs analytical testing of
 - Finished Product
 - Research and Development Materials
 - Stability Samples
 - Raw Materials
- Ensure testing is performed in accordance with cGMP, USP, ICH, FDA and company standards
- Review and approve analytical testing data
- Lead investigations
- Authors/revises SOPs, protocols and data reports
- Tracks and trends data
- Performs method transfer
- Lead qualification and calibration of equipment
- Empower 3 Lab Manager

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.

Required Education and Experience

- Bachelor's Degree in chemistry or relevant field
- Minimum 10 year of experience in pharmaceutical industry performing analytical testing
- Experience with HPLC/UPLC analysis, preferably using Empower 3 software

- Familiar with general laboratory instrumentation and equipment: Karl Fischer, micropipettes, pH meter, analytical balance, vortex, centrifuge, volumetric glassware etc.
- Familiar with GMPs, FDA, ICH and OSHA requirements
- Experience using MS word, Excel, and/or relevant applications
- Must be capable of wearing all protective wear as required by regulations/company standards. This includes, but not limited to; mask, gloves, gown, respirator, safety goggles etc.
- Must be capable of working with small delicate pieces of machinery to complete appropriate analysis in a timely manner
- Must be able to work with chemicals used in sample analysis including acids, bases, and solvents following any special safety precautions as required.
- Must have strong organizational skills and exceptional attention to detail
- Must exhibit punctuality and low absenteeism
- Able to work independently, as well as part of a team
- Able to sit, stand, squat, kneel, reach and walk for prolonged periods of time
- May need to lift up to twenty-five (25) pounds on occasion

Competencies

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

Supervisory Responsibility

This position has no 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.