Lead Stability Coordinator

Full Time
Mt. Laurel, NJ

FLSA Status
Exempt

Job Summary
The Lead Stability Coordinator is a role within a 503B Outsourcing Facility responsible for managing and developing stability studies in accordance with CFR, ICH, and applicable regulatory guidance. This includes protocol development, managing study execution, stability investigation, data management, and data interpretation. The Lead Stability Coordinator reports directly to the Director of Quality.

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

- Ensure stability program meets relevant regulatory guidance
- Support cross-functional teams to ensure requirements are met for product stability studies
- Initiate new and maintain in-progress studies for drug products:
    - Bracketing Matrix
    - Long-Term and Accelerated
    - Maintain Stability Chambers
    - Sample Pulls
    - Coordinate Sample Submission (Internal and External)
    - Oversee Testing Progress and Results
    - Stability Inventory
    - Follow-up/Verification Testing
- Enter, maintain, update, and evaluate samples/results in the stability LIMS module
- Coordinates study execution (i.e., internal and external), and completes stability protocol final report for new and pre-existing data
- Work with QA to assign product shelf life and/or shelf-life extension
- Provide monthly reports of protocol status, upcoming pulls, investigation status, and upcoming studies
- Develop and maintain standard operating procedures (SOP) applicable to the stability program
- Investigates protocol deviations, discrepancies, and out-of-specification (OOS)
- Utilize data to forecast product stability and proactively work with management to decide appropriate remedial action
- Perform risk assessment to determine safety and efficacy of product
- Initiate change controls applicable to the stability program and work with QA personnel for change control execution
- Assist in regulatory audits with the FDA and applicable regulatory bodies
- Assist in the development and execution of relevant corrective and preventative action
- Assist QA personnel in evaluating customer issues, when necessary

Required Education and Experience

- Minimum of 5 years of experience in pharmaceutical manufacturing or 503B outsourcing, without degree
- Minimum of 3 years of experience in pharmaceutical manufacturing or 503B outsourcing, with degree

- Bachelor's Degree in Biological Science, Chemistry, Biomedical Engineering, or relevant field, preferred
- Excellent communication and technical writing abilities
- Extensive knowledge with GxP, FDA, ICH, and OSHA requirements
- Project management experience and/or experience with LIMS or other statistical software are a plus
- Proficient with Microsoft Office applications (Word, Excel, etc.)
- Must be capable of wearing all protective wear as required. This includes, but not limited to, mask, gloves, gown, hairnet, safety goggles, etc.
- Must have strong organizational skills and exceptional attention to detail
- Must exhibit punctuality and low absenteeism
- Able to work independently and as part of a team

Competencies

- Communication Proficiency
- Problem Solving/Analysis
- Quality Oriented
- Results Driven
- Technical Capacity
- Thoroughness
- Troubleshooting
- Time Management
- Work Independently

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

This job operates primarily in the Quality and Manufacturing Areas. This position requires the use of standard office equipment, and frequent standing and walking.

Reasoning Ability

Must have the ability to solve practical problems and deal with a variety of concrete variables in situations where substantial standardization exists. Must be able to interpret instructions furnished in written, oral, and diagram or schedule form.

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.

- Able to sit and/or stand 8-10 hours or more per day
- Able to squat, kneel, reach and walk for prolonged periods of time
- May need to lift up to twenty-five (25) pounds on occasion

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.