Job Title: Quality Control Specialist/Analyst III

We are seeking a talented and motivated Quality Control Specialist/Analyst to join our dynamic Quality team. This position actively supports routine drug substance and drug product release and stability testing for List and client products. This includes participation in transfer and implementation of new analytical methods to support manufacturing and development activities and may include planning and executing verification and validation protocols. This position is primarily responsible for management of the stability program to ensure on time testing and reporting.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Performs GMP testing and associated QC Laboratory operation tasks without errors per applicable SOPs and test methods.
- Develops expertise in assigned assays/techniques.
- Manages the QC stability testing and data reporting schedule. Ensuring that stability samples are collected, tested, and reviewed according to quality requirements, and results reported are valid, accurate, and documented per applicable SOPs and protocol requirements.
- Prepares stability protocols per standard template and client/product requirements.
- Reviews batch records and product specifications as required.
- Analyzes and formats data to support stability evaluation and trending.
- Performs investigations to resolve issues related assay failures, system deficiencies, out of specification results/trends or support product impact assessments, as necessary. Authors deviation, invalid assay and OOS assessments.
- Assist in transfer and implementation of new analytical methods by planning and coordinating execution of method transfer activities. Including ordering of supplies and materials, purchasing equipment, preparation of documents, providing training, coordinating schedules, and working with other team members.
- Assists in equipment and instrument qualification, calibration, and preventive maintenance, as assigned.
- Writes SOPs and reports with minimal oversight.
- Samples raw materials and ships for testing to contract laboratories.
- Supports performance of environmental monitoring of manufacturing rooms (viable and non-viable air sampling, and viable surface monitoring), water systems, media growth promotion studies as workloads require.
- Participates and performs in cross-training to support staff availability within QC department
- Provides data review to ensure data integrity and adherence to standard operating procedures and cGMP's.

QUALIFICATION AND EXPERIENCE

- B.S. or M.S. preferably in biological sciences or related field
- A minimum of 5 year of relevant experience working in Biotechnology or Pharmaceutical industry in a QC laboratory preferred

KNOWLEDGE, SKILLS AND ABILITIES

- Skills and knowledge of general chemical and immunological test methods such as Karl Fischer, Moisture Determination, HPLC, Gel electrophoresis, UV spectroscopy, PicoGreen, Western Blot, and ELISA.
- Compendial testing such as MLT, growth promotion, endotoxin, TOC, and conductivity a plus.
- Advanced knowledge of cGMPs (21 CFR 211 and 21CFR 610), safety and data integrity as relevant to a QC laboratory.
- Experience in executing phase appropriate method qualifications and validations a plus.
- Highly independent and self-motivated and integrates well within a team
- Good organizational skills with ability to meet deadlines and prioritize work on multiple projects
- Excellent oral and written communication skills, ability to organize and present data to draw conclusions including ability to write reports for stability trending and evaluation.
- Must be proficient with computer applications (i.e. Microsoft Office products and Adobe Acrobat).

**If hired, List Labs will require that you provide evidence of your legal right to work in the United States. List Labs will not sponsor applicants for work visas at any time during recruitment or employment.

Apply: https://www.ziprecruiter.com/job/ca8ecde0