



Job Title: Quality Control Microbiology Analyst
Job Type: Regular, Full-time Exempt
Reports to: Quality Control Manager

Summary

The person in this position will support all QC Chemistry activities and participate in the development and transfer of analytical methods into QC for qualification and use on cGMP processing. This person will also be responsible for a variety of cGMP Quality Control testing including raw material, in-process, release, stability, and development testing while ensuring that the scientific quality and the cGMP compliance of the work performed is compliant with current regulatory standards.

Essential Functions

- Support operations in QC chemistry to ensure safety, identity and potency of products in accordance with FDA and ICH guidelines.
- Ensure all QC activities are cGMP compliant and meet high scientific standards.
- Perform cGMP Quality Control testing for multiple projects.
- Coordinate outsourced testing as required.
- Represent QC on project teams and coordinate QC activities with other departments to meet project timelines.
- Ensure adherence to departmental, corporate and regulatory policies for cGMP documentation, including data review.
- Maintain and improve tracking systems and associated databases for sample receipt, analysis, reagents and critical chemicals, and personnel/work scheduling.
- Maintain trending systems for QC results (control charting).
- Review QC data, prepare certificates of analysis, reports and quality documents.
- Support laboratory functions including set up, qualifications, calibration and maintenance programs.
- Participate in OOS/OOT investigations and CAPA (corrective action implementation).
- Write, review and approve QC SOPs, test methods, test records, and technical reports to ensure compliance with site corporate and regulatory requirements.

Essential Knowledge Skills and Abilities

- Experience with development and transfer of analytical methods for biopharmaceuticals
- Strong cGMP compliance experience
- Bioburden
- Endotoxin
- Water Sampling and Testing
- Micro IDs
- Environmental Monitoring
- Trend Reports

Minimum qualifications

- B.S. in Chemistry with 5 years experience in cGMP Quality Control for biopharmaceutical drugs.
- Possess excellent oral and written communication skills.
- Ability to multi-task, prioritize and adjust schedules to meet changing business needs.
- Good work ethic and positive attitude.
- Demonstrated interest in personal career growth and the desire to support and work well in a team.