Associate Director QC Analytical Services

VistaPharm, Inc. - Largo, FL

Job Summary:

The incumbent will be the functional lead for all activities associated with VistaPharm's APIs and drug products analytical method development and optimization. They will be responsible to provide comprehensive analytical testing support for drug substance and drug product testing. This position guides the Quality Control Analytical Support Analysts in the compendial review process as well as the raw material / drug product method development / verification / validation / transfer process in accordance with company SOPs and established cGMP and safety guidelines. Additionally, this position drives Innovation through process improvement as well as the implementation of new technology.

Job Responsibilities:

- Work closely with Manufacturing / Supply Chain, Quality Assurance, Project Management, R&D Analytical Development and Regulatory Affairs to ensure timely development and validation of methods as well as the timely testing and release of materials.
- Work collaboratively with Manufacturing/Supply Chain, to ensure that QC analytical methods are aligned with process needs/capabilities and product requirements.
- Coordinate and oversee analytical methods transfers from R&D Analytical Development to VistaPharm's QC labs.
- Identify, evaluate, and implement new analytical methods and quality control strategies for near term product launches.
- Collection of data and finalization of the reports and summaries required to support regulatory submissions.
- Identify and address technical and validation gaps in analytical methods and QC testing in preparation for product commercialization.
- Manages Compendial review process for methods and specifications to ensure compliance of VistaPharm's analytical testing activities with applicable compendia (e.g., USP, NF) and regulatory guidance documents.
- Manage the development and supplies of reference standards and critical reagents for VistaPharm's new products.
- Contribute to the investigation and resolution of out-of-specification (OOS) and out-of trend (OOT) testing results.
- Serve as primary reviewer of CMC sections related to analytical methods and method validation, specifications, and stability in regulatory submissions.
- Accountable for the QC Laboratory Instrumentation life cycle, including Calibration and Qualification according to established procedures.
- Ensures Compliance with all Applicable SOPs, cGMPs, as well as Safety/Security Policies.
- Direct QCAS Laboratory Operations including recruitment, supervision, and development of QCAS staff. Ensures training and compliance of established company SOPs, VistaPharm policies and procedures and cGMP by subordinate staff.
- Provides SME Support for Internal and regulatory inspections
- Reviews/Approves Stability Assessments conducted as part of the Annual Product Review process.
- Perform all other duties as assigned by management.

Qualification and Requirements:

- Bachelor's or Master's degree in Chemistry, Biochemistry, Analytical Chemistry, or a related field. Advanced degree preferred.
- At least 15 years relevant experience including at least 5 years in a combination of QC and AD and at least 5 years in a management role.
- Outstanding problem-solving skills including the ability to devise and implement practical solutions to resolve complex issues. Ability to effectively prioritize and deliver high-quality results on tight timelines.
- Self-starter with demonstrated ability to deliver high-quality results in a fast-paced development environment.
- Excellent written and verbal communication skills. Accuracy and attention to detail.
- Excellent cross-functional team participation skills.
- Demonstrated expertise in cGMP, ICH, USP/EP, and other global compendial regulations and guidance

Benefits & Compensation:

This position offers a competitive total compensation package, including health benefits (medical, dental, and vision), 401k with company match, life insurance, and paid vacation and personal time.