Quality Control Microbiology Manager

VistaPharm, Inc. - Largo, FL

Job Summary:

The incumbent will assure microbiology laboratory compliance with the FDA regulations, cGMP's and all other applicable international regulatory compliance requirements, applicable department programs, including training, documentation, standard operating procedures, and VistaPharm, Inc. policies and procedures.

The incumbent is responsible for supporting the company's Quality Control efforts and prioritizing the microbiology laboratory work load to align with these efforts. This includes the performance of direct reports and area responsibilities necessary to ensure that Laboratory activities are in accordance to SOPs, cGMPs and FDA requirements and are consistent with laboratory objectives.

Job Responsibilities:

- Supervise and schedule QC microbiologist to complete all routine testing of finished product, API/ Raw materials, and Components within VistaPharm required Turn-Around Times.
- Supervise and schedule QC microbiologist to complete all environmental and USP purified water sampling/ testing within VistaPharm procedural requirements.
- Lead/ Participate in project meetings, manage timelines, and review new materials and components for microbiology testing requirements.
- Lead/ Participate in project meetings, manage timelines, and review all new products for microbiology testing requirements.
- Conduct advanced, compendial-based laboratory method/ specification reviews against USP/NF and other applicable industry standards, in relation to pharmaceutical products.
- Perform microbiology risk assessments on materials and products based on regulatory requirements and VistaPharm quality requirements.
- Lead and/or represent QC microbiology in investigations related to microbiology testing or facility issues. Lead method and/or process improvement investigations for prevention of quality issues.
- Train QC microbiology staff, where qualified and ensure compliance of all staff to VistaPharm training/ GMP requirements. Manage/ update analyst training matrix to ensure appropriate personnel are trained to perform/ support the required laboratory testing.
- Design/ review analytical method transfers and/or participate in co-validation efforts with Analytical Research and Development (AR&D) or Quality Control Analytical Services (QCAS) in relation to pharmaceutical products.
- Support R&D activities for new pharmaceutical products or formulation changes. Provide responses to regulatory agencies for submissions and audit responses pertaining to microbiology questions.
- Support procurement activities related to component and material changes in manufacturer or supplier.
- Identify and implement process improvement goals for the QC Microbiology laboratory.
- Initiate change controls and document change requests and ensure their timely approval/closure.
- Adheres to all applicable procedures, cGMP's, company policies, and all other quality or regulatory requirements (OSHA, DEA, FDA, HS&E, etc.). Ensures all work is performed in

a safe, effective manner, and in compliance with the appropriate industry and regulatory (FDA, DEA, OSHA) standards, and Departmental, Plant, and Corporate quality and Safety goals.

Qualification and Requirements:

- A four year degree in Microbiology or related natural science with experience in a QC Pharmaceutical Microbiology laboratory environment (8-10 years).
- Knowledge of pharmaceutical quality control, regulatory interactions and cGMP is required (8-10 years).
- Previous laboratory supervisory experience (2-4 years)
- Special Skills: Excellent organizational, analytical, mathematical, and computer skills. Good written and verbal communication skills, including presentations to all levels of management. Ability to perform work under pressure and accomplish multiple tasks with efficiency of operations.
- Specialized Training: Fast paced environment; on call nights and weekends to address issues that may arise. Experience working with manufacturing, engineering, and QA to solve departmental and facility issues. Working knowledge of microbiological test methods.
- Experience with Project Management.
- Experience with word process/data programs.

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.