Microbiologist/Manager of QA Microbiology Laboratory

About Ascendia Pharmaceuticals:

Ascendia is a specialty pharmaceutical CDMO company dedicated to developing enhanced formulations of existing drug products and enabling formulations for pre-clinical and clinical stage drug candidates. Ascendia specializes in creating formulations for poorly-water soluble molecules using nano-particle technologies. Ascendia assesses the feasibility of a broad array of formulation options in order to improve a drug's bioavailability and solubility. Ascendia's technologies include nano-emulsions, amorphous solid dispersions, nano-particles, injectable, and controlled release. Ascendia provides development, GMP manufacturing, and testing services - from discovery-stage molecules to life-cycle-management projects - creating formulation solutions with enhanced biopharmaceutical properties suitable for clinical scale-up.

The mission of our company is to provide customized formulation solutions to "salvage" difficult compounds and to create advanced medicines to help patients "prevail" over their disease and enhance quality of life.

About the Position:

- The main role of Microbiologist/Manager within Quality Assurance Team is to provide the daily operation support and manage the Microbiology Laboratory and EM Monitoring Program. The Microbiologist/Manager will schedule testing programs, perform microbial testing, EM monitoring of the aseptic production areas, SOPs writing and review, lab investigation, and documentation under cGMP environments.
- In addition**,** general laboratory operations (ordering supplies, culture media, operating laboratory equipment, sample receipt, lab notebooks, records and data, authoring/review/integrity following good documentation practices)
- Environmental monitoring of classified areas including incubation of samples, reading of results, reporting, and approving data. Environmental monitoring activities include but not limited to contact plates, viable/non-viable counts, microbial ID testing, and operator monitoring. Trending of data for quarterly reports and investigating EM excursions including OOS results. Prepare media, reagents and materials as needed for laboratory testing.
- Determine microbial content and identify microorganisms from products, raw materials and components.
- Be able to perform microbial method qualification and growth promotion.
- Support aseptic media fill process simulations validations.
- Develop and update SOP's and guidelines as needed.
- Maintain records of all tests performed, methods used and final disposition according to Standard Operating Procedures.
- Maintain departmental stock cultures

Key Responsibilities:

- Manage the external labs for testing of raw material, in-process, CCIT, and product release testing per micro specifications
- Schedule and perform the environmental monitoring testing program
- Manage the testing of the samples of the media fill runs
- Handle Microbiology deviations, CAPA, and OOS investigations
- Work in cGMP's, FDA, USP, NSF regulations and guidelines
- Other assigned duties

Qualification:

- BA/BS/MS in Microbiology/Biology with 5+ years' experience in pharma or micro-lab environment is required.
- Prior experience with data review, Writing SOPS, Change Controls, out of specification investigations and report writing under cGMP is recommended.
- Working knowledge of aseptic manufacturing environmental monitoring of sterile areas is preferred
- Compliance with all cGMP standards, safety and environmental regulations and company SOPs.
- Works independently
- Strong communicator and collaborate effectively with coworkers and between departments.
- Knowledge of cGMP regulations and FDA guidance related to manufacturing of sterile and non- sterile pharmaceutical products is a plus
- Leadership and management skills and ability to foster a team environment.
- Be flexible and able to work under pressure and meet project timelines.