

JOB PURPOSE:

Executes the activities of QC Microbiology Laboratory by following approved microbiological and chemical test procedures and ensure their delivery in an accurate and timely manner following proper safety precautions. Also provide QC microbiology support to the Aseptic Manufacturing and validation process.

DUTIES & RESPONSIBILITIES:

- Familiar with Drug Regulations, Pharmacopeia's and Regulatory requirements.
- Authoring SOP's and Test Methods when required.
- Assurance of cGMP and GLP compliance in the QC Microbiology Laboratory.
- Responsible for laboratory cleanliness and biohazard removal.
- Performs Microbiological Tests and studies by following the established procedures referenced in the official sources.
- Collection of samples (Raw Materials, Excipients, Validation, In-process and Finished product samples) for microbiological / chemical testing.
- Conducts validations studies and routine tests related to Bioburden Test, Bacterial Endotoxin Tests, Particulate Matter Test and Sterility Tests.
- Preparation of microbiological media and diluents by following laboratory procedures.
- Quality Control Testing of microbiological media and reagents.
- Calibration, Cleaning and Maintenance of the laboratory equipment.
- Calibration, Cleaning and Maintenance of the laboratory instruments.
- Ensures the QC support in Aseptic Manufacturing (Environment Monitoring) and Validation (Steam Sterilization, Dry Heat Sterilization, Cleaning and Disinfection) process.
- Environment Monitoring of Aseptic / Non-aseptic Manufacturing areas and Trending of microbial data obtained from EM/Utilities/Raw Materials/In-process and finished products testing and prepares the periodical summary report.
- Assists in OOS/MDD investigations to find out the root cause and facilitates the implementation of appropriate CAPAs.
- Maintenance of Laboratory inventory.
- Responsible for maintaining the microbiology isolates obtained from EM and Utility Monitoring Program.
- Follow established health and safety procedures and policies related to QC Microbiology Laboratory operations.

Quality Control Microbiologist

PENN LIFE SCIENCES

Department: QC Micro-lab

FLSA Status: Exempt

Reports to: Supervisor

Location: 38 Cabot

- Perform other related duties as required and assigned by Microbiology Laboratory Management.
- Assists and coordinates the samples send to external laboratory for testing.
- Excellent Oral and Written English communication skills.
- Fluent in Microsoft Office word, Excel and PowerPoint.

ESSENTIAL SKILLS & EXPERIENCE:

- Must have a Minimum Bachelor's Degree in Microbiology or related disciplines and One year of experience (Fresh Graduates are welcome)

PHYSICAL DEMANDS: While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

The job demands here are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. This job description is not intended and should not be an exhaustive list of all principal job elements essential for recruitment and selection, for making fair job evaluations and for establishing performance standards. The percentage of time spent performing the various job duties is not absolute. The incumbent, who has the right to amend, modify, or terminate this job in part or in whole. This document is not a contract for employment.