Microbiology Analyst

Work Schedule

12:00 pm to 8:30 pm

Job Title

Microbiology Analyst I

FLSA Status

Non-exempt

Job Summary

The Microbiology Analyst I is responsible for supporting microbiology procedures, assisting in investigations, and performing routine analysis of raw material and finished product according to established specifications and procedures.

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- Assist in method validation for sterility, bioburden, and endotoxin of drug products including, but not limited to, injections, ophthalmic preparations, oral tablets, and oral liquids
- Perform and/or assist in investigations related to sterility assurance and environmental monitoring
- Perform routine analysis of finished product and raw material according to established specifications and procedures relating to:
    - Sterility
    - Bioburden
    - Endotoxin
    - AET
    - Growth Promotion
- Perform atypical particulate inspection on finished product
- Support sampling and microbiological testing on facility water (WFI, CS, etc.)
- Review and approve data related to sterility, bioburden, AET, and endotoxin testing of finished product and/or raw materials
- Perform technical review of test results for completeness and compliance to cGMP to ensure that documentation, controls and traceability are in place to maintain integrity
- Prepare and review preparation of media, reagents, test samples and equipment as required

- Prepare microorganisms for identification
- Understand and demonstrate aseptic technique
- Maintain laboratory cleanliness and inventory of microbiology supplies
- Familiar with GxP (Good Manufacturing Practice, Good Laboratory Practice and Good Documentation Practice)
- Assist with environmental monitoring and microbiological trend reports

Required Education and Experience

- B.S. degree in Microbiology, Biology or related scientific field
- Minimum 1 year of experience in a microbiology laboratory or pharmaceutical industry
- Knowledge of good analytical and laboratory techniques, GxP, USP and FDA requirements
- Knowledge in statistical data analysis and its application to pharmaceutical or compounding processes and quality controls
- Must exhibit good analytical, writing (GDP), interpersonal and organizational skills
- Must be able to meet deadlines
- Must be detail oriented and have multi-tasking capabilities with ability to prioritize
- Must exhibit strong computer skills including but not limited to software packages supporting statistical data analysis, word processing, and project management programs
- Must have the ability to work in a fast-paced environment
- Must exhibit excellent problem resolution skills
- Must be able to work independently and as part of a team
- Must exhibit punctuality and low absenteeism
- Must be able to sit, stand, reach and walk for prolonged periods of time

Eligibility Qualifications

- Must develop knowledge of 21 CFR Part 210 and 211 for cGMP operations
- Must be capable of wearing all protective gear (gown, hair bonnet, mask, beard cover, gloves, goggles) and maintain good personal hygiene (makeup, jewelry and other cosmetics are prohibited from the production areas)
- May be necessary to work extended hours as needed
- May require weekend work

Competencies

- Communication Proficiency
- Time Management
- Organizational Skills

- Problem Solving/Analysis
- Quality
- Results Driven
- Technical Capacity
- Thoroughness

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

This job operates primarily in a controlled laboratory environment. This position requires the use of standard office equipment, and frequent standing and walking.

Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

- Able to sit and/or stand 8-10 hours or more per day as needed
- May sit, stand, stoop, bend and walk intermittently during the day; may be necessary to work extended hours as needed
- Finger dexterity to operate office equipment required
- Ability to lift up to twenty (20) pounds on occasion

Position Type and Expected Hours of Work

This is a full-time position. Because of the nature of the business, work schedules may vary at times.

The scheduled work hours are 12:00 pm to 8:30 pm.

Travel

No travel is expected for this position.

Health & Safety

Stokes Healthcare, Inc. and its subsidiaries will be required to be fully vaccinated as a term and condition of employment to safeguard the health of our employees from the hazard of COVID-19. This policy complies with OSHA's Emergency Temporary Standard on Vaccination and Testing (29 CFR 1910.501).

Disclaimer

The above job description is intended to describe the general nature and level of work being performed by employees assigned to this job. It is not designed to capture or illustrate a comprehensive list of all responsibilities, duties, and skills required of employees assigned to this job.

AAP/EEO Statement

Stokes Healthcare is an Equal Employment Opportunity and Affirmative Action Employer.