

Company:	Brogan Pharmaceuticals	Location:	US-IN-Crown Point
Status:	Full Time, Employee	Job Category:	Biotechnology and Pharmaceutical
Relevant Work Experience:	3 to 5+ years	Career Level:	Supervisor Microbiology Environmental Monitoring
Education Level:	Bachelor's Degree	Aseptic Manufacturing	Parenteral Products

Job Description

Job Responsibilities / Activities:

The Microbiology Supervisor is responsible for leading the Microbiology department and development of programs, processes, and procedures at Brogan Pharmaceuticals.

Job Duties include but are not limited to: The person maintains the quality and facilities, ensuring regulatory compliance, and provides regulatory guidance in the application of their job.

- Applies Good Laboratory and Manufacturing Practices in all areas of responsibility.
- Demonstrates and promotes the company vision.
- Establish and comply with proper documentation and training in compliance with 21 CFR Part 210 & 211
- Leadership role for Quality Assurance Department including implementation of systems and procedures focused on process improvement and defect prevention as related to microbiology and sterility assurance.
- Pursue efficiency improvements and cost reduction efforts consistent with regulatory compliance.
- Issue, investigate and follow-up on environmental reports such as EAN/EAR/EIR to ensure use to ensure all reports are closed within 14 days (to support site product release goals). Includes evaluation of incident and decision for sampling requirements.
- Implementation of EM program improvement initiatives to ensure compliance with FDA, PDA and ISO requirements.
- Facilitation of the Environmental Monitoring team, including data review and analysis, maintaining the EM data trending spreadsheets, preparation of graphs and reports for team and management review, etc.
- Function as a technical resource for Micro, Manufacturing and Validations for aseptic processing and EM.

Education Experience/Requirements: To be successful in this role you will require:

- **BS Degree in Science required.** Life Science curriculum such as Biology, Microbiology preferred.
- Fully experienced in all Microbiology lab operations with a minimum of 3-5 years service.
- **Special Skills:** Demonstrated technical writing, strong interpersonal and prioritization skills required. Also, strong analytical skills, ability to assertively interact with people at all levels of the organization. Extensive knowledge of environmental monitoring programs desired. Has expertise in microbiological principles and applications related to microbial ID, validation, and clean room technology.
- **Specialized Training:** Trained in cGMP for laboratory operations and compliance to regulatory guidelines with working knowledge of microbial ID systems, (VITEK, Biolog, etc...), USP sterility and bioburden test methods to include use of Vaporized Hydrogen Peroxide (VHP) technology.

Brogan Pharmaceuticals is dedicated to the achievement of equality of opportunity for all its employees and applicants for employment without regard to race, color, religion, sex, gender identity, sexual orientation, marital status, age, national origin, disability, veteran status or any other protected group status under federal, state or local law.

Please direct inquiries or deliver resume and CV to: hr@broganpharma.com