Principal Microbiologist

Reach your career goals with Eirgen Pharma, your future could be here

Would you like to be part of a company that has the courage, innovation, and capability to improve and enhance patient lives across the globe?

Eirgen was founded in 2005 and since then we have continually grown and now employ over 180 employees at our site in Waterford. Our strengths lie in our capability to rapidly introduce new products and add additional volume to existing products - ensuring supply for new product launches and expanding market opportunities.

What makes us different is that while we continue to grow our business, we have still maintained that small company feel to our culture which enables us to ensure that our employees are always front and centre in everything we do. By creating a progressive and dynamic working environment, where hard work and enjoyment aren't mutually exclusive, we have created a high performing, people-centric culture which allows us to work in an environment where the focus is always on ensuring that the patient comes first.

About the Job

The Principal Microbiologist is responsible for providing scientific and technical leadership for all microbiological aspects of site operations, including Environmental Monitoring (EM), Cleaning Validation, Contamination Control, and Utilities Monitoring.This role acts as the site Subject Matter Expert (SME) for microbiology, supporting Manufacturing, Quality Assurance, Engineering, and Validation in maintaining a compliant and contamination-free manufacturing environment.

The Principal Microbiologist will develop and oversee microbiological control strategies in line with current regulatory expectations (EU GMP Annex 1, FDA, ISO 14644), lead investigations into contamination events, and ensure continuous improvement in environmental and cleaning programs. The role involves mentoring the Eirgen Team &supporting audit readiness.

Main focus of this role includes but is not limited to:

1. Environmental Monitoring (EM) Program

- Lead the design, implementation, and continuous improvement of the site EM program across manufacturing, packaging, and support areas.
- Define EM sampling plans, frequencies, and alert/action limits for environments based on risk assessments and regulatory expectations.
- Trend and review EM data routinely, identifying potential issues or emerging risks.
- Lead or support investigations into environmental deviations or out-of-trend (OOT) results.
- Ensure EM practices, documentation, and reporting align with cGMP and data integrity standards.

2. Cleaning Validation & Verification

- Act as SME for all microbiological aspects of cleaning validation and cleaning verification.
- Define microbiological acceptance criteria, sampling locations, and recovery methods for product contact and non-product contact surfaces.
- Review and approve cleaning validation protocols, reports, and periodic reviews to ensure scientific soundness and regulatory compliance.

- Evaluate and trend cleaning verification data to identify patterns and recommend corrective actions where required.
- Support change control assessments for cleaning agents, equipment, and processes that may impact microbial control.

3. Contamination Control & Site Hygiene

- Own or co-own the site's Contamination Control Strategy (CCS) to ensure consistent microbial control across facilities, processes, and utilities.
- Coordinate and monitor the site hygiene program, including cleaning, sanitisation, and housekeeping controls.
- Provide microbiological input to facility design, material flow, and cleaning schedules to prevent contamination and cross-contamination.
- Conduct risk assessments to identify areas for improvement and ensure preventive controls are in place.

4. Utilities & Environmental Support Systems

- Oversee microbiological monitoring of water systems (Purified Water, Potable Water) and compressed gases used in manufacturing and laboratory operations.
- Review, trend, and assess microbiological data to ensure systems remain within alert and action limits.
- Support validation and requalification of utility systems from a microbiological standpoint.
- Investigate deviations or excursions and ensure robust CAPA implementation.

5. Laboratory Oversight & Technical Support

- Provide oversight and technical guidance to the laboratory team to ensure compliance with cGMP and site procedures.
- Ensure timely and accurate execution of microbiological testing, including bioburden, endotoxin, total viable counts (TVC), and water testing.
- Review and approve microbiological data, reports, and laboratory investigations.
- Support method validation, equipment qualification, and laboratory audits.

6. Investigations, Risk Assessment & CAPA

- Lead or provide expert input into microbiological investigations and root cause analyses.
- Conduct risk assessments to evaluate contamination risks and determine appropriate controls.
- Ensure CAPAs are scientifically justified, effectively implemented, and verified for effectiveness.
- Support QA and Manufacturing with microbiological input during deviation reviews and change control.

7. Documentation & Reporting

- Author, review, and approve microbiological protocols, reports, and standard operating procedures (SOPs).
- Prepare microbiological trend reports and contribute to Annual Product Reviews (APRs) and Management Review meetings.

- Ensure all documentation meets data integrity (ALCOA+) and cGMP expectations.

8. Training, Mentoring & Leadership

- Deliver microbiology and contamination control training to site personnel.
- Promote a strong microbial awareness and quality culture across all departments.

9. Audit & Regulatory Support

- Serve as the Microbiology SME during internal audits and external regulatory inspections.
- Provide microbiological data, reports, and responses to queries confidently and accurately.
- Support closure of audit findings and implementation of continuous improvement actions.

10. Continuous Improvement

- Identify and drive continuous improvement initiatives in environmental monitoring, cleaning, and microbial control programs.
- Support implementation of new technologies or process optimisations to improve data accuracy and efficiency.
- Remain up to date with current regulatory guidance and industry trends in pharmaceutical microbiology.

About you

You are qualified to a minimum of degree level in Microbiology, Biotechnology, or related Life Sciences discipline (M.Sc. desirable). Minimum 7 years' experience in a cGMP-regulated pharmaceutical or healthcare manufacturing environment.Strong knowledge of Environmental Monitoring, Cleaning Validation, Water System Microbiology, and Contamination Control.

Experience leading microbiological investigations, risk assessments, and data trending. Solid understanding of cGMP, ICH Q9/Q10, EU GMP, and FDA expectations for microbiological quality. Demonstrated leadership in mentoring, training, and cross-functional collaboration.

You have a quality and compliance mindset and will draw from many skills including adaptability, planning, multi-tasking and time management. You have strong initiative and form positive relationships, you enjoy collaborating, gaining knowledge, continuous improvement and solving problems.

Working at Eirgen – What to expect

At Eirgen, we have developed a diverse, people-centric, high-performance culture where people are enabled to achieve their potential.

If you are working at Eirgen, then we think you've got something special. Our employees are high-performing and work as part of a cohesive team, they are dedicated people who are driven to succeed and are rewarded with competitive salaries and an attractive range of benefits including opportunities for career progression and continuing education.

Apply for the above role by sending your CV to opportunities@eirgen.com including the job title in the subject.