Megan Sullivan

Senior Microbiologist

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SUMMARY

Senior microbiologist with 9 years in pharmaceutical QC microbiology, leading investigations and root cause analysis for 2 aseptic fill lines. Experienced in contamination control, environmental monitoring, sterility testing and method validation under GMP and FDA regulations for aseptic processing. Mentors analysts and explains microbiology data clearly to QA, manufacturing and inspectors.

EXPERIENCE

Senior Microbiologist

04/2022 - Present

Valley Forge Biologics

King of Prussia, PA

Biologics manufacturer with 2 aseptic fill lines supplying US and EU markets.

- Lead microbiology investigations and root cause analysis for sterility, EM and water excursions, closing **22** deviations on time in 2025.
- Own the contamination control strategy for 2 aseptic fill lines, including EM site selection and disinfectant efficacy studies.
- Represent QC microbiology in FDA and EU inspections, with no lab observations issued during the 2024 FDA inspection.
- Mentor 7 analysts and review method validations, SOPs and data packages before QA approval.

Microbiologist II

07/2019 - 03/2022

Delaware Valley Pharmaceutical Laboratories

Exton, PA

Sterile and non-sterile drug product manufacturer.

- Validated rapid microbial methods for bioburden and endotoxin, cutting release testing time from 7 days to 2.
- Authored 25 SOPs and test methods and revised the EM trending program for 3 cleanroom areas.
- Investigated recurring mold recoveries, traced the source to an HVAC drain pan and confirmed the fix over 6 months.

Microbiologist I

06/2017 - 06/2019

Brandywine Contract Testing

West Chester, PA

GMP contract lab for pharmaceutical and device clients.

- Performed sterility, bioburden and endotoxin testing on 100+ client samples a month under GMP.
- Identified isolates by Gram stain and VITEK 2, building a site isolate library used in quarterly trending.
- Ran growth promotion tests on every incoming media lot, roughly 90 lots a year.

SKILLS

Root Cause Analysis

Contamination Control

Environmental Monitoring

Sterility Testing • Bioburden

Endotoxin • Method Validation

Aseptic Processing • GMP

FDA Regulations

EDUCATION

Bachelor of Science

05/2017

The Pennsylvania State University

University Park, PA

Microbiology

CERTIFICATES

Certified Quality Auditor (CQA)

ASQ

10/2023