Rachel Whitfield

Microbiologist

Microbiologist with 4 years in sterile pharmaceutical QC labs in the Research Triangle, testing 40+ product lots a month. Experienced in microbiological testing, bioburden, environmental monitoring and aseptic technique under GMP and FDA regulations. Writes clear SOPs in Microsoft Word, brings attention to detail to data review and has strong communication skills with QA.

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Raleigh, NC

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Experience

Microbiologist

05/2024 - Present

Piedmont Biologics

Raleigh, NC

Sterile injectable manufacturer with 12 classified cleanroom suites.

- Perform sterility, bioburden and endotoxin testing on raw materials, water and finished vials for **40+** lots a month.
- Manage environmental monitoring for 12 cleanroom suites and trend results monthly, flagging adverse trends to production within 1 day.
- Author and revise SOPs and test methods in Microsoft Word, completing 15 document updates ahead of a 2025 FDA inspection.
- Investigate out-of-specification results with QA and manufacturing, closing 9 investigations with root causes and CAPAs on time.

QC Microbiology Technician

06/2022 - 04/2024

Carolina Contract Laboratories

Morrisville, NC

GMP contract testing lab serving pharmaceutical and device clients.

- Tested 200+ water and in-process samples a month by membrane filtration and pour plates under GMP.
- Collected viable air and surface samples in ISO 5 to ISO 8 areas using strict aseptic technique and gowning.
- Built Microsoft Excel trend charts for water and EM data that QA reviewed at each quarterly quality meeting.
- Identified isolates by Gram stain and MALDI-TOF, growing the client isolate library to 300+ entries.

Skills

- Microbiological Testing
- Aseptic Technique
- Environmental Monitoring
- Bioburden
- GMP
- FDA Regulations
- Microsoft Excel
- Microsoft Word
- Attention to Detail
- Communication Skills

Education

Bachelor of Science

05/2022

North Carolina State University

Raleigh, NC

Microbiology