THOMAS H. REED

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PROFESSIONAL PROFILE

Quality control professional, seeking consulting roles, supporting the manufacturing of sterile, low bioburden drug substance and drug product. Microbiological testing related to raw materials, in-process and final product testing to ensure quality. Management of aseptic processing, contamination control programs supporting environmental control of manufacturing cleanrooms and processes. Significant expertise in creating audit ready Annex 1 compliant microbiology systems.

WORK EXPERIENCE

Sr. QC/QA Consultant –L. Reed Global QA, Inc. BioPharma Client 02/2025 – Current

- Environmental and utility qualification of new GMP manufacturing facility and remediation for existing facility.
- Upgrading of QC laboratory operations to expand testing capabilities and support requirements for GMP Manufacturing.
- Support for activities related to Quality Management Systems: CAPA, Deviations, Change Control, Out of Specification results, Document Control.
- Remediation activities to ensure compliance with updated FDA and EU Annex 1 requirements for sterile manufacturing.
- Support for customer and regulatory audit responses and completion of corrective actions.

UNIQURE, Lexington, MA 11/2016 – 07/2024

Associate Director of Quality Control, Microbiology (01/2022 – 07/2024)

Conducted qualification and maintenance of environmental and utility monitoring program for controlled and classified manufacturing areas to ensure microbial control, including execution of contamination investigations and implementation of corrective actions.

- Preparation and successful completion of multiple global agency audits for approval of gene therapy products.
- Development and maintenance of contamination control program used in controlled classified areas that supported drug substance and drug product manufacturing.
- Oversight of QC Microbiology quality systems: deviations, change controls, corrective and preventative actions (CAPAs), document revisions related to microbiology operations.
- Executed microbiological method qualifications, supporting late-phase gene therapy products.
- Prepared microbiology laboratories for preapproval inspection (PAI) and completion of EMA and FDA PAI inspections, with no major observations identified in microbiology operations.

Senior Manager of Microbiology (01/2019 – 01/2022)

Manager of Quality Control, Microbiology (11/2016 – 01/2019)

Managed QC of microbiology operations, supporting manufacturing of AAV gene therapy products.

- Managed environmental and utility monitoring programs, supporting cell and viral culture processes and aseptic processing of sterile drug products.
- Oversaw microbiological testing related to raw material, in-process, and final drug substance and product release.
- Managed scheduling microbiology and sample management resources required to support manufacturing processes.
- Reviewed and approved method verifications related to product sterility, endotoxin, and bioburden.
- Managed quality systems events related to department (change control, deviations, out of specification, invalid and aborted assays, and environmental monitoring excursions). Ensured timely closure of investigations, including assessment of product impact to aid in disposition decisions.

SUN PHARMA, Billerica, MA 02/2009 – 11/2016

Senior Manager of Quality Control, Microbiology, Incoming Quality Control (07/2016 – 11/2016)

Accountable for implementation of global quality standards for microbiology operations.

- Managed quality systems related to microbiology and incoming QC: investigations, deviations, CAPA, change controls, and quality metrics.
- Managed microbiology operations, supporting two manufacturing sites.

Manager of Quality Control, Microbiology, Incoming Quality Control (10/2011 – 06/2016)

Managed QC of microbiology and incoming raw material groups, supporting aseptic processing of commercial drug products. Delegated staff for QC inspections, including sampling, testing, and disposition of raw materials and components used for the manufacturing of parenteral pharmaceuticals.

- Scheduled QC of microbiology resources, ensuring support provided during active manufacturing, including environmental monitoring, in-process bioburden, and endotoxin testing.
- Oversaw microbiological final release sterility and endotoxin testing for commercially distributed pharmaceuticals, ensuring material was suitable for release to market.
- Supervised microbiological monitoring of utilities (clean steam, WFI, and purified water) to ensure systems were operating in a state of microbial control.
- Reviewed and approved method validations related to product sterility, endotoxin, and bioburden.
- Approved purchases of supplies and materials used to support QC operations.
- Oversaw microbiological activities related to qualification of state-of-the-art Isolator Aseptic Fill and Finish facility.
- Represented QC of microbiology during FDA regulatory, contract manufacturing, and internal audits, guaranteeing microbiology operations were compliant with FDA standards.
- Provided technical oversight for sterility assurance of commercially distributed drug products, including process simulation, aseptic operator qualification, component and material sterilization validation, and equipment qualification.

ADDITIONAL EXPERIENCE

PHARMALUCENCE INC., (acquired by Sun Pharma), Billerica, MA

Supervisor of Microbiology

ALKERMES CORPORATION, Boston, MA

Senior Microbiologist Contractor

HISTOGENICS CORPORATION, Waltham, MA

Lead Microbiologist

WYETH BIOTECH, Andover, MA

Quality Control Manager, Quality Control Microbiology

Senior Supervisor, Quality Control Microbiology

Group Head, Quality Control Microbiology

CHARLES RIVER LABORATORIES, Wilmington, MA

Associate Manager Bacteriology, Special Projects

Senior Supervisor Bacteriology

Supervisor of Bacteriology

Senior Laboratory Technician

EDUCATION

Bachelor of Science (BS), BOSTON UNIVERSITY, Boston, MA