

Nikunj Shah

Microbiologist

+91 98989 98158 📞

nikunjs111@gmail.com ✉

Ahmedabad, Gujarat, India, 380015 📍

👤 Summary

Microbiologist with **15 years of extensive experience** in pharmaceutical Quality Control, specializing in **sterility assurance, microbial testing, cleanroom controls, and regulatory compliance**. Previously held **second-in-command (Deputy Lead)** role in the QC Microbiology Lab. Experienced in **microbiology lab setup, audits, documentation, QMS compliance, training, environmental monitoring programs, method validation, and troubleshooting**. Skilled in managing audits, documentation, procurement and continuous improvement initiatives aligned with guidelines.

Strong exposure to **USFDA, WHO audits** along with hands-on expertise in **OOS/OOT investigations, BET and Sterility testing, root cause analysis, and aseptic practice guidance**.

📊 Skills

- ✓ Microbiology Lab Setup & Compliance
- ✓ SOP Design, Review & QMS Documentation
- ✓ Sterility, BET, MLT, EM, Water Testing, Endotoxin Controls
- ✓ ISO & GMP Audit Readiness (USFDA/WHO)
- ✓ Microbiology Training (Operators, Analysts, QA Teams)
- ✓ Microbial Trend Analysis & CAPA Implementation
- ✓ Cleanroom Qualification & Environmental Monitoring Plans
- ✓ Vendor Qualification & Raw Material Microbial Controls
- ✓ Budgeting, Forecasting and Inventory Management
- ✓ Microbial Identification and Characterization
- ✓ LIMS and QMS Software
- ✓ Microbial Method Validation

📁 Experience

Senador Laboratories Limited (Insud Pharma)

Ahmedabad, India

Assistant Manager

May 2017 - Aug 2025

Key Responsibilities:

- Acted as the **second lead of the microbiology laboratory** supervising a team of analysts.
- Supervised a team of microbiologists in executing quality control procedures for raw materials, inprocess materials, and finished products.
- Oversaw routine and critical microbiological activities:
 - BET Testing (performed analyses in front of USFDA inspectors)
 - Sterility Testing
 - MLT / AET
 - Environmental Monitoring
 - Water System Microbial Control

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- Disinfectant Efficacy

- Managed **QMS documentation**, change controls, deviations, audit responses, and risk assessments.
- Develop and review SOPs, STPs, Work Instructions and Validation Protocols.
- Conduct internal training on aseptic techniques, GMP practices & lab safety.
- Prepared the **annual micro lab budget**, consumable planning, and calibration schedule.
- Successfully faced multiple **USFDA, WHO audits** as reviewer for microbiology.
- Implemented robust **microbial trending programs** and reduced sterility failures by preventive controls.
- Conducted internal training on **aseptic behavior, contamination control and microbiology techniques**.
- Handle vendor qualification, material approval & inventory planning.
- Work closely with QA, Production, R&D and Engineering teams.
- Participated in the development and validation of new microbiological methods and technologies.
- Led the implementation of a new microbiological testing system, significantly increasing efficiency and reducing turnaround time.
- Provided technical guidance and training to staff on microbiology testing techniques, regulatory requirements and best practices, ensuring consistent performance and adherence to quality standards.
- Managed and controlled the procurement and inventory of microbiology testing materials, ensuring availability and quality of reagents, media and equipment.
- Identified and implemented cost effective measures to optimize QC processes, reducing testing expenses without compromising quality standards.

Zydus Biologics (Cadila Healthcare Ltd.)

Ahmedabad, India

Sr. Executive

Oct 2010 - May 2017

Key Responsibilities:

- Handling the analysis and routine microbiological practices with respect to Sterile and Non -sterile Formulation.
- Responsible for Implement, follow and maintain the Lab for GLP compliance and maintaining Analysis Records in the Microbiology Laboratory.
- Water analysis, Microbial Testing, Operation and calibration of Total Organic Carbon Analysis.
- Personal Monitoring, Environment Monitoring, Swab Testing in sterile plant.
- Media Preparation and autoclaving.
- Isolation, Identification, Preservation and Maintenance of Environment and Water Isolates.
- Preservation and maintenance of ATCC reference culture.
- Container Closure integrity test by Microbial Ingress Test.
- Validation and Calibration of Laboratory Instrument like HPHV steam sterilizer, Incubator, Micropipette, Laminar Air Flow, TOC- Analyzer.
- Validation and testing of the sterility Test, Microbial Limit Test, Bacterial Endotoxin Test for different

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products.

- Validation and efficacy of the Disinfectant.
- Particulate Matter testing of Finished product Samples.
- Procuring the required material for Microbiology Lab.

Hester Biosciences Ltd.

Kalol, India

Officer

July 2010 - Oct 2010

Key Responsibilities:

- Start the career as production officer to handle the routine activity and learn the egg based poultry vaccine preparation.

🎓 Education

M.Sc. – Microbiology

Year-2010

Sardar Patel University

- Conducted independent research project on “Studies on HALOPHILES: Functional Diversity and Amylase Production”.

B.Sc. – Microbiology

Year-2008

Sardar Patel University

12th - Science

Year-2005

GSHSEB

10th

Year-2003

GSHSEB

🏆 Awards

- Presented the poster on “STEM CELL TRANSPLANTATION” and have got 3rd prize in poster competition in ARIBAS, NEW VV Nagar (2009).

📄 Projects

- Completed a project titled as “Studies on HALOPHILES: Functional Diversity and Amylase Production”, as part of dissertation. (In academic year 2009-2010).

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Language

Gujarati

English

Hindi

Personal Information

Date of Birth : 9th March, 1988

Gender : Male

Marital Status : Married

Languages known : Gujarati, English, Hindi.

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