

Kinnari Shah
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Professional Summary:

Result-oriented leader with extensive experience in sterile and non-sterile Formulation/API GMP laboratories. Adept in aseptic techniques, regulatory compliance, analytical quality assurance, and people management. High drive for quality.

Professional Experience:

Eurofins Biopharma Product Testing UK Limited (Mar 2022 – Present) **Senior Team Leader, Microbiology**

As a Senior Team Leader at Eurofins Biopharma Product Testing UK Limited, I have been entrusted with the management of the Microbiology department. My responsibilities encompass overseeing GMP testing, method development, and regulatory compliance. I am an active member of the Leadership Team and lead a team of four.

Main Responsibilities:

- Led a high-performing team, optimizing productivity while maintaining stringent quality standards.
- Developed and executed strategies for future business unit success.
- Fostered team growth through team-building, coaching, motivation, and recognition.
- Ensured compliance with GMP and regulations, handling audits and inspections.
- Implemented meticulous documentation, schedules, safety protocols, and cleanliness measures.
- Proficiently conducted Microbial Limit Tests (MLT), Bacterial Endotoxin Testing (BET), Growth Promotion Tests (GPT), sterility testing, and method validations to ensure product safety and regulatory compliance.
- Maintained accurate documentation to support audit-readiness and timely filing.
- Orchestrated work schedules, cross-training, and resource optimization for adaptable service delivery.
- Conducted analytical analyses for uninterrupted service during challenges.
- Strategically optimized resource utilization during training for enhanced efficiency.
- Ensured consistent service levels and unwavering quality through investigation of performance variations.
- Managed CAPA, change controls, and contributed to procedure and report development.
- Supported equipment calibration, qualification, and maintenance.
- Actively proposed and implemented continuous improvements.
- Contributed to departmental forecasting and budgeting.
- Supported the commercial team and played a role in the site leadership team.
- Served as a member of the Microbiology Global Council.

Achievements:

- Successfully led the re-opening initiative for MHRA Audit, ensuring strict compliance and operational readiness.
- Implemented comprehensive training modules for microbiology testing, enhancing team skills and proficiency.
- Spearheaded crucial area change controls, conducted risk assessments, and maintained a 100% compliance rate for equipment calibration.
- Strategically initiated cross-training and mentoring programs, yielding increased team productivity, broader knowledge base, and a substantial reduction in errors.

- Played a pivotal role in updating Annex 1 guidelines, ensuring alignment with the latest industry regulations for environmental monitoring.
- Served as an Internal Auditor, conducting audits to ensure adherence to quality standards and regulatory requirements.
- Changed culture of the department from one of under-performance to a highly motivated unit. This was achieved by raising performance standards, effective recruitment, and individual mentorship.

B&S Group (Feb 2021 - Mar 2022)

Role: Sr. QC Microbiologist

Key Responsibilities:

- Oversaw all Microbiological activities, reporting directly to QA head and QP.
- Conducted Microbiological testing of water, Microbial Limit Tests for non-sterile products, and Preservative Efficacy Tests in compliance with Pharmacopeia requirements.
- Managed Microbiological media, including conducting Growth Promotion Tests.
- Performed Environmental monitoring and handled Microbial cultures and isolates.
- Ensured quality compliance through QAMS, handling Change Control, OOT, OOS, Deviation, Incident, and investigation processes.
- Implemented cGLP, GDP, and cGMP in the lab, maintaining online documentation.
- Qualified sterile and non-sterile plant areas, conducted BET, and performed trend analysis.
- Prepared SOPs and provided training to team members.

Achievements:

- Streamlined microbiology operations, reducing costs and improving efficiency.
- Implemented a rigorous sterility assurance program to meet regulatory standards.
- Validated critical systems, including water system, TOC instruments and autoclaves. Effectively implemented PET and stability study timepoints to ensure product quality assurance, contributing to improved team productivity and knowledge base.

Bristol Laboratories Ltd. (July 2020-Feb 2021)

Role: Team Leader – Microbiology Lab

Key Responsibilities:

- Promoted for exceptional performance.
- Oversaw all microbiological activities.
- Conducted water microbiological testing and Growth promotion Tests.
- Managed microbial limit tests.
- Oversaw environmental monitoring and culture maintenance.
- Ensured quality compliance and documentation.
- Conducted instrument calibrations and trend analysis.
- Validated culture maintenance and performed product specific MTL Validation.
- Maintained stringent quality standards and streamlined processes.

Achievements:

- Successfully validated temperature mapping.
- Implemented cGMP, GDP, and cGLP standards, enhancing regulatory compliance and product quality in pharmaceutical operations.

Glenmark Pharmaceuticals Ltd. (Nov 2014 to Apr 2019)

Role: Senior Officer – Microbiology Lab

Key Responsibilities:

- Promoted from Jr. Officer, recognized as an FDA-approved technician.
- Conducted chemical and microbiological testing of various water types.
- Proficient in sterility testing, endotoxin testing, and environmental monitoring.

- Expertise in SOP preparation, growth promotion tests, and analytical reviews.
- Managed microbial cultures, documentation, and calibration of critical instruments.
- Ensured regulatory compliance and documentation.

Achievements:

- Successfully faced US-FDA audits for sterile and non-sterile products.
- Achieved consistent compliance with MHRA, WHO, EDQM, and EU-GMP standards.

Wockhardt Ltd. (July 2013 to Nov 2014)**Role: Officer – Microbiology Lab****Key Responsibilities**

- Promoted from an apprentice to Officer for consistent commitment.
- Conducted microbiological testing and environmental monitoring.
- Specialized in culture maintenance, method validations, and regulatory compliance.
- Maintained high standards in microbiology operations.
- Contributed to regulatory compliance and documentation.

Achievements:

- Implemented cGLP, GDP, and cGMP standards, demonstrating expertise in validation and successfully navigating regulatory audits by MHRA, WHO, EDQM, and EU-GMP.

Volunteer Work:

- Actively participated in Circle conversational pairs from November 2019 to February 2020, contributing to meaningful interactions and connections.
- Successfully completed the Namaste Training course in January 2020, enhancing communication and support skills.
- Volunteered as a Namaste carer at St Joseph's Hospice, Hackney, demonstrating compassion and assistance to patients.
- Dedicatedly served as a Homerton helper at Homerton Hospital, providing valuable support to healthcare facilities and patients.

Education:

- M.Sc in Microbiology Sardar Patel University, Vallabh-Vidhyanagar - 2013
- B.Sc in Microbiology Sardar Patel University, Vallabh-Vidhyanagar - 2011