

**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