

Resume

Kailas Ramchandra Gawle
QC Microbiology

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Objective:

Efficient professional with 14 year's experience and a proven knowledge of pharmaceutical services. Aiming to leverage my skill to successfully fill the Microbiologist role at your organization.

Profile:

- Review of microbiology department documents with preparation of standard procedures.
- Performing DHS validation, autoclave validation, AHU system validation, Incubator validation, Water system(WFI,Purified) validation with their protocol implementation.
- Reviewer and strength in sterility, BET, MLT, clean room facility EM, area/personal qualifications, media fill validation.
- Handling of quality management document & implements if any in QMS.
- Audit handling –Regulatory/customers audit.
- Responsible for management microbial cultures, microbiological media, GPT, & their records.
- Qualification and requalification of instrument/equipment and controlled area.
- Method Validation and verification as per laid down protocol for miscellaneous studied like BET,MLT, sterility test with EM for sterile areas.
- Ensuring proper water analysis finished products analysis's raw material analysis & its verification report releases and rejection respective.
- Trending for water environmental monitoring on their availed results.
- To monitor cleaning and waste management for used analytical media.
- Preparation, implementation & maintenance of microbiological SOP's.
- To ensuring all personal maintaining Good laboratory practices and good documentation practices.

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- Microbiology laboratory setup for different area i.e. (clean room design, IQ, OQ, PQ for different types of equipment with validation/calibration, microbial culture development,).

Experience:

- ❖ **Lab in-charge -QC Microbiology (From April 2024 to current working)**
Intas Pharma Ltd Ankleshwar, (Oncology API based with Paranteral required product.)
- ❖ **Asst. manager –QC.** (March-2023 to April 2024)
*Sudeep nutrition Ltd. (**nutrient based Product preparation-Poicha plant**), Baroda, Gujarat, India.*
- ❖ **Sr.Executive –QC Microbiologist.** (March-2021 to Feb-2023)
*Kilitch healthcare Ltd. (**Parenteral preparation-Rabale plant**), Navi Mumbai, Maharashtra, India.*
- ❖ **Executive –QC Microbiologist.** (Jun 2017 to March 2021)
*Kores india Ltd. (**API plant for dosage requirement-Roha plant**), Raigad, Maharashtra.*
- ❖ **Executive –QC Microbiologist.** (October 2014 to May 2017)
*Piramal Health Care Ltd. (**Dosage formulation-Mahad plant**), Raigad, Maharashtra, India*
- ❖ **Sr. Officer QC Microbiology. (April 2013 to October 2014)**
Kopran Ltd. L-1, (Sterile API manufacturing-Mahad Unit), Raigad, Maharashtra, India.
- ❖ **Chemist QC Microbiology.** (March 2010 to April 2013)
*Ipca Laboratories Ltd., (**Dosage form manufacturing- Athal Unit**),Silvasa, India.*

● Validation Performed:

- Performed autoclave validation, Water system validation, Analyst Qualification, Miscellaneous Hold Time Studies, Disinfectant Validation and Efficacy Study etc., Qualifications & Calibration of Laboratory Instruments.

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- **Educations:**

- Master of Science (**Microbiology**) June -2009, North Maharashtra University, Jalgaon,
- Bachelor of Science (**Microbiology**) April-2007, North Maharashtra University, Jalgaon.
- FDA approved certified by Maharashtra FDA for Microbiology section year 2015.

- **Skills:**

Quality management in departmental work. Fast decision taking ability with team. Leading audit handling performance in every regulatory or any kind of audit. Fast tracking for Validation of all types of instrument and equipment's as like microbiological instrument s as well as chemical analytical instrument.

- **Audits Handled:**

- Faced regulatory inspections as, US-FDA, MHRA, WHO, Indian FDA,etc. and Vendor inspections.

- **Personal information:**

- **DOB:-** 26/09/1986.
- **Address:** A/P-surwani, Akrani, D-Nanurbar 425414.MH
- **Married.**

- **Declaration:**

Hereby declare that the details furnished above are true the best of my knowledge.

Date:

Place:

(Kailas Ramchandra Gawle)