

# MAHESH ARUN KALE

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Quality Control & Assurance  
Industry Preference: Pharmaceutical  
Location Preferences: PAN India/Overseas

## QUALITY CONTROL PROFESSION:

**M.Sc. (Analytical Chemistry) professional** above 17 years of experience in **pharmaceutical industry** and accomplished in managing the **quality control laboratory activities**.

## PROFILE SUMMARY:

- Technically competent performance driven professional with rich experience in pharmaceutical Quality Control Laboratories of **OSD, Dry Syrups, Suspension, Ophthalmic formulation, Sterile dosage form (Lyophilized product, prefilled syringe) and API manufacturing** Companies.
- Exhibited leadership in Quality Control activity for **QMS** events and deriving the CAPA using appropriate tools like **Brain storming, GEMBA WALK, FISHBONE analysis and Why-Why analysis**.
- Successfully completed preparation of **investigation reports** and documents related to closure with prescribed management of laboratory investigation.
- In-depth knowledge about the concepts like **Good Laboratory Practice (GLP), Regulatory audits, GMP & Quality Assurance**.
- Experience in handling of **Finished Product, Stability, In-Process, Raw material** and **Analytical Method validation** sections independently and ensures the completeness of analysis within stipulated timeframe.
- Handled sophisticated analytical instrument such as **UPLC, HPLC, GC, Dissolution, LCMS, GCMS, XRD, UV Spectrophotometer, FTIR**, and Malvern Master Sizer 3000.
- Expertise in areas such as **Resource Management and Quality Auditing** with regulatory and non-regulatory pharma formulations units.
- Handled software for investigation **Track-Wise**, quality management **Caliber LIMS, Lab ware LIMS, DMS, and SAP, Empower-3 FR6**.
- Recognized as:
  - **Certified Technical Staff in Chemical and Instrumentation from FDA, Maharashtra State through Mylan Laboratories Limited.**

## Significant Accomplishments:

- Showed competency in handling QC operations to achieve the desired results for organization.
- Pivotal in streamlining processes through measures such as SLA Improvement and Quality Index Terminology.
- Led the development of cost-effective ways of working to ensure quality, compliance, service and safety.
- Reduced the quality failure by identifying areas of failures and taking steps to rectify the system.
- Took initiatives through various training programs in coordination with training teams and took corrective actions on the basis of quality checks.
- Core member of Regulatory Audit compliance team and successfully complies the FDA audit observations.
- Providing feedback to top management based on quality audits & rendering suggestions for improvement.
- Participating in implementation of Stability Sample management in Labware LIMS.
- Participating in implementation of Custom fields in Empower software.
- Conducting and compliance of **6S audits** in lab.
- Conducting inspections at various stages to ensure safety & quality specifications are being met with, without any slippages.

## ORGANIZATIONAL EXPERIENCE

Since Dec-2022 to till date as Quality Control Associate Manager with Biocon Limited, Hyderabad

### Key Result Areas:

- Managing format investigation to find out root cause of out-of-specification, out-of-trend results, analytical incidence and taking corrective & preventive actions.
- Reviewing and approving the Standard Operating Procedures (SOPs), Instrument Operating Procedure, Specifications protocols and reports related to QC, maintenance and production.
- Participating in quality & process improvement initiatives along with technical services, R&D, QC, QA, Engineering Departments, Supply management to map the requirement as per the business need, ensuring compliance with laboratory practices as per the quality control procedures.
- Handled the SOP simplification project in coordination with Corporate Quality team.
- Software in to quality such as Labware LIMS 3.4.0, SAP, Documentum and Empower 3.6.1, FR6 for roll out routine usage.
- Interfacing with people at all levels, managing healthy work environment and inculcating bonded teamwork with high work ethics;
- Extending support to Manufacturing Team, Supply Chain, QA, and Regulatory Affairs Department with various query response by providing suitable justification as per guidelines.
- Managed a team of 22 members and engaged in allocating them tasks as per their capabilities.

## PREVIOUS EXPERIENCE

Since Mar'10 - Dec'22 with Viatris (Mylan Laboratories Limited) Sinner, Nashik, Maharashtra as QC: Deputy Manager

### Significant Accomplishments:

- Managed a team of 30 members and engaged in allocating them tasks as per their capabilities.
- Conducted effective failure investigation with identification of CAPA within stipulated period. Formal investigation to find out root cause of out-of-specification, out-of-trend results, analytical incidence and taking corrective & preventive actions.
- Recognised as best performer and leader.
- Involved in weekly review meeting with QA, PDL, RA, ADL, R&D and F&D department as Core member of QC.
- Collaborated work with QA, PDL, RA and Production on planning and scheduling.
- Review of finished product results and log instrument break down history through SAP.
- On job training as necessary to develop skills of person, Analyst Qualification for newly join employee and supervision.
- Review of Analytical raw data, Chromatographic data.
- Empower project creation and audit trail review
- Inspection at various stages to ensure Lab safety and Quality Standard.

Since Jun'07-Feb'10 with Verna, Goa as QC: Management Staff

### Significant Accomplishments:

- Perform physical and analytical test for Stability and FP samples and complete within timeframe.
- Ensure in-use stability samples simulation activity for injections and Syrup.
- Perform incubation and pull out of stability samples and stability management.

## ACADEMIC DETAILS

- **M.Sc. (Analytical Chemistry) from North Maharashtra University, Jalgaon in 2007 with 62.00%**
- **B.Sc. (Chemistry) from North Maharashtra University, Jalgaon in 2005 with 56'57%**

## PERSONAL DETAILS

**Date of Birth:** 7<sup>th</sup> July 1984 || **Languages Known:** English, Marathi, Hindi || **Address:** Mr. Arun Kadu Kale, At Post - Moykheda Digar, Tal - Jamner, Dist. - Jalgaon, PIN - 424 206, Maharashtra.