

RAJENDER REDDY BANKITI

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Hyderabad, Telangana-India

PROFILE SUMMARY

A dynamic quality professional with over 17 years of experience in pharmaceutical industry, leading crossfunctional teams in Quality Control and Quality Assurance. A collaborative team player with excellent communication skills, strong problem-solving abilities.

EDUCATION

- Post graduation (**M.Sc.**) in **Organic Chemistry** from **SRTM University**-2007, Maharashtra- India.
- Graduation (**B.Sc.**) in **Chemistry** from **Osmania University**-2002, Hyderabad, Telangana-India.

PROFESSIONAL SKILLS

- Analytical Review | Caliber LIMS | Documents Verification | Audit trail
- Month Projects creation | Backup activity | Empower and Standalone Instruments
- Laboratory Incidents (LIR & LOR) in Quality Control | Qualifications (IQ, OQ and PQ) | Computer System Validations
- cGMP | GxP | Stability Management | Working Standard Management.
- QMS | Out of Specifications (OOS) | Out of Trend (OOT) | Regulatory support | Audit and Compliance.

AUDITS FACED

- Regulatory audits like USFDA, TGA, EDQM, MHRA, ANVISA and Korean FDA.
- Customer audits, internal audits conducted by CQA and Self inspection audits conducted by cross functional departments.

Assistant Manager- Analytical Quality Assurance | Feb-2017 to Present.

Aurobindo Pharma Ltd Unit-5, Pashamylaram-Hyderabad.

- Effectively delegating the responsibilities to team and closely monitor the progress and fulfilment.
- Ensuring the all-time audit readiness of the quality control laboratory, highlight and mitigate the risks leading to critical observations during regulatory, customer and internal inspections.
- Review of Laboratory Incidents (LIR & LOR) based on discrepancies occurred during the Quality Control analysis and ensure clean report with compliance.
- Review and approval of Finished Products, Intermediates and Raw materials by Caliber LIMS.
- Handling of regulatory, customer and internal audits by accommodating the quality control laboratory visit, explaining quality systems and drafting of audit responses.
- Identifying gaps in existing system to devise new systems address the gaps.
- Deep dive into investigations to find the root cause for OOS, OOT, deviations and market complaints.
- Perform Backup of all Quality Control Analytical Instruments (Instrumentation and Standalone).
- Evaluation of cross-functional team recommendations and final approval.
- Participation in CFT meetings to provide problem-solving and quality improvement.
- Review and approval of computerized system validation (CSV) documents.
- Review and approval of SOP's, Spec & MOA's, APQR's, OOS, OOT, and Deviation reports.
- Review and Approval of calibration and preventive maintenance of Analytical Instruments.
- Audit trail verification of chromatographic systems and standalone Instruments.
- Performing Gemba walks as per schedule and defining tasks upon observations.
- Conducting periodic self-inspections in cross-functional departments.
- Responsible for taking up any additional tasks assigned by HOD/Designee.
- User ID creation, Enable and removal of Users in Analytical Instruments with respective software applications as a QA Administrator role as per SOP.
- Prepare and Ensure Active Users for Instrument wise (Analyst, Reviewer, Lab Manager and Administrator) and User Privileges for Quality Control Department.

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Senior Executive – Quality Control | May-2015 to Feb-2017

Sai Life Sciences Ltd Unit-4, Bidar, Karnataka.

- Planning and delegating analysis tasks to team members around the clock in shifts.
- Investigating OOS, OOT and market compliance samples in Quality Control.
- Reviewing of checklist, sample sets and instrument methods before start the analysis.
- Periodic Calibration data of HPLC, GC and other Analytical Instruments.
- Coordination with vendors for qualification (IQ, OQ & PQ) of new instruments.
- Analysis of protocol-based samples as part of investigation troubleshooting.
- Compiling analytical data, reporting and releasing analytical test results post-analysis.
- Informing to the supervisor, any discrepancies occurred during analysis and ensure clean reports.
- Responsible for analytical method verification and method transfers as per approved protocols.
- Management of working standards, in-house standards and reference standards.
- Preparation of Protocols for Quality Control requirements in line with STP.

Officer Quality Control | May-2012 to April-2015

Jubilant Life Sciences Ltd, Mysore, Karnataka.

- Evaluation of working, in-house, and reference standards against pharmacopeia standards.
- Calibration of analytical instruments HPLC, GC, KF Titrator and Analytical Balance as per schedule.
- Chromatography Analysis of API, Intermediates, Stability samples and Raw materials by handling of Instruments like Waters with Empower, Agilent with EZ Chrome and Shimadzu with LC Solution software.
- Responsible for analytical method transfer (direct or indirect) against approved protocols.
- Analysis of stability samples within the timelines.
- Evaluation of working standards, in-house standards against reference standards and maintain consumption record of usage.

Senior Executive Quality Control | November-2007 to April-2012

MSN Laboratories Ltd-Unit-I, Rudram, Hyderabad.

- Analysis of in-process, raw materials, Intermediates and finished product tests of Instrumentation and Standalone.
- Instruments handled like HPLC (Waters, Agilent both PDA and UV detectors), GC (Agilent and shimadzu both Head space and Auto injector) with Empower, EZ chrome and LC solution softwares.
- Analysis of PD Lab samples using chromatographic and non-chromatographic analytical techniques.
- Generating AR No's after receipt of GRN's from Warehouse and ATR's from manufacturing team.
- Sampling and of in-process, raw materials, intermediates and API samples as per approved procedures.
- Attending cGMP, GLP, GDP, ICH and E.H.S (Safety) trainings laid down by the organization.

PERSONAL DETAILS

Address: Plot No. 70, Annapurna Enclave, Chandanagar, Hyderabad-500050, Telangana, India
Father's Name: Krishna Reddy
DOB: August-22, 1981
Languages: English, Hindi and Telugu.
Hobbies: Continuous learning and playing cricket

DECLARATION

I solemnly declare that the information in this curriculum vitae is true to the best of my knowledge.

RAJENDER REDDY BANKITI