RATAN KUMAR MISHRA

*A multi-faceted professional accustomed with proven skills, targeting Opportunities in **Analytical Developement/Quality Assurance** and **Quality control** with an organization of repute in*

Pharma/Chemical/Agrochemical industries

ratanmishra166@gmail.com +91-8058787990/8824480644

Quality Management Systems

Audit & Compliance Management / Vendor Qualification Management

Integrity, Data Back Up & Data Security

Analytical Raw Data Monitoring

Team Management & Leadership

- A competent professional with 13 years of experience in supporting **Analytical Development Calibration and Qualifications of Instruments, Instruments Troubleshooting & Stability Studies**
- Impressive success in implementing various standards to improve the **Product Quality**, **Deviations, Change Control, and Failure Investigations**, monitoring & measuring performance and driving new steps.
- Capable of providing **innovative ideas** to teams and provide best solution
- Proven capability in individually managing the **quality control laboratory activities**, administered
- Effective in managing **risk analysis** and initiating measures to reduce risks in the product quality
- Contributed to audit readiness and performed various audits of **USFDA,MHRA,NABL,ISO 9001, ISO 14001, ISO 45001, RC, REACH SEDEX, Halal, Kosher, TFS, Ecovadis , GMP plants, Contract Testing Labs,** and so on, faced successful audits from internal company groups, regulatory agencies, and customers
- A keen planner with proficiency in enhancing quality process operations, increasing operational efficiencies in compliance with quality guidelines

Soft Skills

Knowledge Purview

- ICPMS (i CAP RQ) Themo scientific
- ICP OES Themo scientific
- IC (ION Chromatography) Mettler Tolledo
- HPLC (Shimadzu-LC-2010-CHT), Waters, AGELENT
- GC (Perkin Elmer With GC Solution)
- FT–IR Spectrometer(Perkin elmer-SPECTRUM-100) & Shimadzu
- UV/Visible Spectrometer(Perkin elmer-LAMBDA-35) & Shimadzu
- Potentiometer (Mettlet Tolledo)
- Particle size analyzer
- Polarimeter AUTOPAL-V (RUDOLF)
- Karl fisher (Mettler Tolledo T-50),Metrohm, Manul
- DSC
- Melting Point
- Muffle Furnace
- Lod Instrument
- Wet Analysis(Physical & chemica testing)

Education

- **2010:**M.Sc. EC/Mica from S.O.S Jiwaji University, Gwalior (M.P)
- **2007:**B.Sc. from Purvanchal University, Jaunpur (U.P)
- **2004:** 12TH From UP Board
- **2002:** 10TH From UP Board

Key Result Areas

- Handling of change control, deviation, OOS & Market complaints.
- Schedule to assess and ensure that facility and quality system meet the cGMP , GMP & GLP regulatory standard and establishment company policies and standard.
- IMS internal &MR Audit for ISO 9001, ISO 14001 & ISO 45001.
- Prepare Vendor audit report as per defined timeline & share with vendor for compliance l.
- Communication with vendor for compliance & CAPA.
- Review of Audit compliance report of CAPA implementation & it's effectiveness
- Review and verification of quality index received from each site.
- Handling of all validation activities carried out in the plant.
- Schedule analytical method development of various pharmaceuticals & chemicals products for their estimation of active contents by HPLC & GC.
- Monitoring the Analytical activities pertaining to allocated group.
- Documenting evidence covering identification of instruments, frequency of re-calibration, calibration status.
- Formulating budgets, SOPs & policies, designing systems & processes and work instructions for conducting laboratory trials.
- Maintaining and calibrating various analytical instruments like GC,HPLC, IR, KF, Balance and so on
- Maintaining Instrument Logbooks and Instrument Calibration Records &ICP,HPLC, GC, IR, UV, KF Systems.
- Reviewing Analytical raw data to ensure validity and accuracy; monitoring the Analytical activities pertaining to allocated group.
- Preparing general SOPs, raw data forms, method SOP's .
- Involving in SOP writing and imparting training to the analytical team on SOP's, also instrumental in mentoring junior chemists on analytical instruments, laboratory procedures, analytical method development.
- Maintaining and calibrating various analytical instruments including GC, HPLC, IR , KF, Balance and so on .
- Monitoring adherence to quality systems, comply with quality standards & maintaining requisite documents.
- Preparing review and report compilations of analytical method development data and calibration reports, Protocol and report for drug product method transfers.
- Tracking technical queries, regulatory deficiencies, change controls/deviations through database.
- Interfacing with customers, surveyors for complaints and organizing retesting after product transfers and clarification of test results, test methods used and testing requirements.
- Working with the Operations Department and Technical Services for effective operational control, organizing test runs of new feed, specific product specification requirements.

Highlights:

- Monitored inventory of chemicals & consumables; purchase requests and technical evaluation of services and product.
- Successfully completed the task of setting up of GLP Analytical Laboratory equipped with qualified and calibrated instruments.

Experience

Sr. Manager QA/QC
Sumitomo Chemical India LTD **Since Sep. 2023 to Till**

Manager QA/QC **Feb.2022 toAug2023**
Vatva ,Ahmedabad

Asst. Executive QA/QC **June.2016 to Feb. 2022**
PI Industries Ltd. Udaipur

Officer **Apr'2015 - Jun'2016**
Lupin Ltd. Mandideep, Bhopal

Officer QA/QC **Sep'2012 - Apr'2015**

HPL Additives Ltd. Faridabad, Haryana

Research Chemist **May'2011 - Jun'2012**
Parabolic Drugs Ltd. R&D Center, Barwala (Punjab)

Personal Details

Father's Name- Akshaibar Nath Mishra
Date of Birth: 31st July 1988
Marital Status- Married
Languages Known: Hindi,English,Sanskrit,Gujrati
Address- 404/A, Tankar-3 Residency Vatva Ahmedabad