Dinesh Kumar Rajput

+91 8427652596, +91 9997024652

rajputdinesh010@gmail.com

Roop Nagar Punjab, 140001

SUMMARY

A focused professional with 17 **years** of work experience working as a Deputy Manager Quality. SME Quality- Quality Management System, Process Validation, Quality Control, Qualification, Analytical Method Validation, Method Verification and Method Transfer. (Instrument/Wet Analysis and GLP),

SKILLS

- Good Leadership skills.
- SAP (Systems Applications and Products in Data Processing).
- OOS / OOT Investigations.
- Analytical Method Validation, Method Verification & Methos Transfer.
- Knowledge of Track wise and Quality One system for handling of Change Management, Quality Risk Management, Quality Incident and deviation.
- Regulatory requirement understanding
- Problem-solving
- Team relationship building
- Communication skills

ACCOMPLISHMENTS

- Lead Investigator for USFDA approved plant
- Site QC Lead and managing team with leadership skills.
- Lead investigator for handling of investigations as per Fish bone Daigram and regulatory requirements

EXPERIENCE

Current – 13.07.2015 to till Date

Centrient Pharmaceuticals India Pvt. Ltd. | Toansa Punjab India

Current Position: Deputy Manager - Quality

- Working as a Deputy Manager Quality where handing team of approx. 20 people working in Finish Product (HPLC Lab), Wet Lab, GLP and Ongoing stability study (from last approx. 1 year) and timely release of quality product (Finish Products & Raw Materials).
- Responsible for All Analytical Method Validation, Method Verification and Method transfer as per USP general chapter and regulatory requirement.
- Preparation and Review of Analytical Method Validation / Verification / Transfer Protocols & Reports.
- Responsible for Planning and Release for Finish Products through SAP.
- Earlier working as Compliance Lead responsible for Laboratory compliance. and investigation of OOS/OOT/Deviation/Market Complaints of Quality as per quality management system.
- Responsible to maintaining the TPT (Through Put Time) of Finish Products as well Raw Materials as per internal quality system.
- Responsible for Calibration of analytical equipments as per inhouse calibration schedule and planner.
- Responsible for working standard management. Qualification of working standards as per certified reference standards (BP/EP/IP/JP/USP).
- Responsible for Review of audit trails of analytical instruments.
- Responsible for implementation CFR 21 part 11 compliances.
- Responsible for the Compliance of Quality management system i.e. Management of Change Controls, Quality Risk Management, Quality Incidents and Deviations through Track wise/ e-QMS.
- Responsible to Maintain the site KPI matrix on target (weekly as well as monthly basis).
- Responsible for review of Quality trends report by collecting, analyzing and summarizing information associated change controls, Deviations, out of specification and Quality Incidents.
- Coordinated and participated in internal and external quality management system audits to guarantee product and quality specifications.
- Responsible for Preparation and Review of SOP's.
- Responsible for Product Quality Review and preparation of annual product stability reports.
- Indirect participation in Market complaints, Product recalls (Active participation in Mock recalls).

- No overdue CAPA, Change controls, Deviations, Risk assessment and closure of long pending actions after charge handover.
- Site cGMP approved trainer.
- Site Safety champion for Handling of Gas wares during analysis.

CERTIFICATIONS

- Approved Chemist in Instrument / wet Analysis under Punjab Drug controller.

AUDIT EXPOSURES

- **USFDA**
- **MHRA**
- **TGA**
- **ANVISA**
- **CDCSO**
- **Many Customers Audits.**

PERSONAL PROFILE

- Father's name: Late Sh. Ved Prakash Singh
- Mother's Name: Late Smt. Rajeshwari Devi
- Date of birth: 15 June, 1982
- Gender: Male
- Marital status: Married
- Nationality: Indian
- Hobby: Listening music, Reading

ADDRESS

- Correspondence Address : H. No. 76, Ram Krishan Colony, Roop Nagar, Punjab India 140001 (Near Jyoti Gas Agency).
- Permanent Address : Village : Barkatpur, Post : Sabalpur Bita, District : Bijnor (UP) 246732

REFERENCES

- Mr. Manjeet Singh : Associate Director Sustainability (Ranjeet Avenue Roop Nagar Punjab, Mobile No. +91 9814633821)
- Mr. Lalit Sharma (Head Regulatory Affairs (Sunny Enclave Chandigarh, Mobile No. +91 9915776282)

- Responsible for presenting and participating in monthly site operational review, MQM, cross functional discussions on new projects, new vendor qualification.
- Responsible for internal and external audit handling, CAPA response and CAPA effectiveness.
- Preparation and review of Process Validation Protocols and Process Validation Reports for QC related activities.
- Preparation, review, and approval of SOPs / Work Instructions / formats.

03/2014 - 07/2015

IPCA LABORATORIES LTD. | Dehradun (UK), India

Position: Executive- Quality Control

- Responsible for Review of analytical Data of Finish Products / In process samples / Stability Samples.
- Worked as site QC QMS Lead for investigation of OOS/OOT, Deviations. Lab Incidence through Trak wise system.
- Responsible for Planning of Finish products / Raw Materials / Stability Samples in absence on section in-charge.
- Responsible for preparation of COA of finish Products and submitted to QA.
- Responsible for Analytical Method Validation / Method Verification and Method transfer by HPLC.
- Responsible for review of Quality trends report by collecting, analyzing, and summarizing information associated change controls, Deviations and Quality Incidents.
- Responsible for Analytical laboratory compliance, Trending of Incidents, OOS and OOT based on type of error on quarterly and annual basis, APSR preparation for stability trend evaluation of batches.
- Trending and monitoring of analyst performance on the quarterly basis.
- Quality management system activities (OOS, OOT, Quality Incident, Deviations, Change controls on Track-wise.
- Responsible for calibration of analytical equipments as per inhouse calibration schedule.
- Preparation and review of analytical methods, SOPS & Work instructions.

06/2006 - 10/2013

DSM Sinochem Pharmaceutical India Pvt. Ltd. | Punjab, India

Position: Chemist / Officer - Quality Control

- Analysis of Finish Products using HPLC and GC system.
- Analytical Records / Data preparation as per good laboratory practices.
- Handling of Master Control, SAP, Track wise efficiently.
- Handling and Calibration of HPLC, GC and Head Space GC.
- To Prepare & Compile the validation data of material analyzed by HPLC for process Validation.
- Method validation of Finish Products on HPLC.
- Monthly audit trail review and backup of QC instruments.
- Good knowledge of basic laboratory techniques for working, understanding of equipment's and basic processes.
- Preparation and standardization of volumetric solutions, Qualification of working standards.
- Filling the OOS/ OOT format and checklist and logged with QA.
- HPLC Column washing / conditioning / Saturation.
- GC Column Conditioning.
- Lab hose keeping.

EDUCATION

- **2003 – 2005 : M. Sc – Analytical Chemistry** (CMCA: Commercial method of chemical analysis) form Gurukul Kangri University Haridwar (UK) with **First division** (Full Time).
- **2009 – 2011 : M. Sc. – Organic Chemistry** from C.M.J. University Meghalaya. (Correspondence) with **First Division**.
- **1999 – 2002 : B. Sc. – Chemistry, Physics & Math** from MJP Rohilkhand University Bareilly. (Full Time) with **First Division**.
- **1999 : 12th (Physics, Chemistry & Math** from RJP Inter college Nangal Sotti Bijnor (UP). With **First Division**.

(Dinesh Kumar Rajput)