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Looking forward to a challenging career in an organization, where I can utilize my professional, management and technical skills and work at a position where my ability to work hard and innovative decision making would highly benefit the organization.

Professional Experience

04/2015 - 05/2023

QC Team Leader (Raw Material Section), Assistant Manager (Quality Control), Sanofi India Pvt Limited, Verna, Goa, India, Solid dosage forms.

Management of routine laboratory activities. People management (16 direct reports). Impart training and develop people. Responsible for material review, release/rejection through SAP Athena. Providing technical support to third party testing laboratories. Provide technical support for new projects and analytical method transfers. Management and review of protocols, SOPs, Specifications, change controls, deviations/CAPAs, investigations via Geode+, Phoenix. Attend regular OPEX meeting, projects. Responsible for tracking of Monthly /quarterly/yearly KPI's/KQI's at lab. Ensure cGMP, GLP and HSE is maintained at workplace. Member of recruiting team in recruitment of personnel for QC. Management of water system reference standards and retention sample area. Conduct regular meetings and interaction with laboratory analysts, peers and SLT. Provide required technical support to production. Lead all quality control matters, with both internal and external stakeholders. Ensuring in maintaining high Environmental Health and Safety standards. Support company and department goals, projects, and performance. Provide employee reviews and mentoring to staff. Responsible for CAPEX of raw material section. Timely scheduling of calibration, preventive maintenance of analytical instruments. Timely procurement of lab consumables and other resources. Actively supported in QC re modelling, PAL MAL. Qualified internal auditor and Supplier auditor.

Finished product Section (Designee to Finished Product, Stability section lead).

Plan and executive daily laboratory activities as designee to department head.

Daily intra department coordination for timely release of batches.

Plan and direct analytical method transfer in accordance with standard operating procedures.

Responsible for planning of process validation, equipment qualifications, cleaning validation, performance verification of instruments.

Review and investigate Quality control Deviations, Change controls, lab incidences, out of specification and out of trend results.

Support and execute analytical method development, analytical method transfers and method equivalency.

Evaluation of methods(verification) as per pharmacopeia.

Conduct internal audits.

Manage client correspondence to site quality audits.

Review and approve Quality control records.

Perform temperature/humidity mappings of retention sample rooms and stability chambers.

Execution of Lean and Six Sigma concepts and practices.

Proficient with Lean sigma tools, SAP, MS Office.

Impart training and support in people development.

Responsible for batch releases through SAP.

Ensure cGMP, GLP and HSE is maintained at workplace.

Contact: Upon request

Achievements

Consistent achievements in maintaining zero raw materials exceeding 10 days.

Achieved PCT<7 days for bulk products.

Timely closure of investigations and CAPA:92%

Increased OEE of equipment's by developing alternate analytical inhouse methods.

Reduction in analytical incidence by 41 %. Reduced material release time by 30%. (PCT)

Internalized MOA that was outsourced by25 %.

Enhanced OEE by 27%.

Accomplished KPI's within stipulated time.

Developed alternate supplier in case of monosource and Cost reduction.

Harmonized and de harmonized specifications wherever required to reduce testing time.

Developed people on Analytical techniques and instruments such as HPLC, GC, UV, FTIR etc.

Reduction in Incidence by 30 % by simplifying specifications and ways of working.

01/2011 - 02/2012, 06/2012-03/2015

Instrumentation laboratory Head (Quality Control), Choksi Laboratories Limited (Contract testing laboratory), Verna, Goa India.

Managing day today activities with regards to Laboratory testing for multidisciplinary samples e.g., Finished product, RM, Stability samples, Environmental samples, water testing, soil testing etc. Coordination with customer for sample related queries.

Ensuring compliance and managing regulatory and customer audits.

Always ensured audit readiness.

Review of test methods for quotations required.

Managed overall laboratory activities while respecting timeline for delivering results to the customers. Performed method verification, method validations and working standard qualifications whenever required.

Delivered to customers under pressure situations.

Training and mentoring staff on various analytical techniques and effective communication skills. Performing IQ, OQ and PQ of instruments. Calibration of instruments such as HPLC (VWD, RI, PDA and Manual Injector), GC (Liquid injector and Head space), AAS (Flame and Hydride Technique), UV-Vis Spectrophotometer, FTIR and Dissolution Test Apparatus.

Analysis of Raw materials and finished products using HPLC, GC, ICP-MS and AAS techniques Preparation, and implementation of SOP's and STP's. Checking and review of QC related records like analytical reports, logbooks.

Measurements of raw materials and finished products using UV-Vis Spectrophotometer and FTIR. Wet chemistry parameters using, Karl Fisher Titrator, Disintegration apparatus, Friability apparatus, TLC, Dissolution, Melting point apparatus, Muffle 3 furnace, LOD. Familiar with GMP and GLP environment.

Contact: Upon request

02/2012-05/2012

Officer Quality Control Lupin India Limited, Goa, India.

Analysis of Raw materials and finished products using HPLC, GC,techniques Preparation, and implementation of SOP's and STP's. Checking and review of QC related records like analytical reports, logbooks.

05/2008 – 05/2010 Project chemist (Chemical Oceanographic Division) National Institute of Oceanography, Dona Paula, Goa, India.

Responsible for analysis of volatile compounds using GC (FID, ECD, and TCD). Measurement of trace metals using AAS. Measurement of nutrients using Auto Analyzer, TOC and UV-VIS spectrophotometer. Responsible for testing of Fuel gases, oil samples, Halocarbons, Atmospheric gases. Measurements of water parameters such as pH, temperature, salinity, dissolved oxygen, turbidity. Calibration of the above listed instruments

Countries worked and visited during research activities: Southern Ocean, South Africa, Chile.

Contact: Upon request

05/2005 – 05/2006 Trainee Chemist Reliance Energy Limited Goa, India Power generation Industry Sancoale, Goa.

Responsible for boiler water analysis. Treatment of ETP and wastewater outlets. Responsible for cooling water analysis and monitoring of cooling tower. Online dosing of chemicals. DM plant operation. GLP

Contact: Upon request

Audits faced

MHRA USFDA WHO Goa FDA German FDA Russian regulatory GQA Customer audits

Instruments (Operation, performance verification & troubleshooting)

HPLC (Agilent, Waters, Shimadzu) (Empower, Open lab, EZ chrome software) Caducee interface. GC (Agilent, FID/Headspace) (Empower, Open lab, EZ chrome software) ICPMS, GCMS, LCMS (Agilent) AAS (Analytical Jena) FTIR (Shimadzu IR Affinity). FTNIR Perkin Elmer Raman Analyser (Nano Ram) Alpine jet Sieve shaker Brookfield viscometer Melting Point apparatus (lab India MR-VIS). Dissolution tester (lab India DS14000+, DISSO 2000 and electro lab and dissolution tester DT 1000). UV spectrophotometer Shimadzu UV-1800 having Lab solution software. Potentiometer or Autotitrator (Metrohm 905 titrando having software tiamo 2.5. KF Autotitrator).

Trainings undergone

Insights of personal discovery Reporting Safety Vigilance Data 2022 Corrective and/or disciplinary actions management standards Data integrity Management of Quality maturity Index. Recognize an ethical issue and overcome your biases to report it. Reporting safety Vigilance Data.

Certificates

Pharmaceutical training (08/2010-12/2010) Derex Laboratories, Hyderabad, India. FDA Approval as expert staff in chemical and instrumentation section. (12/2014 – Present) IELTS (11/2019 – Present) Listening:7.0 Reading:6.0 Speaking :8.0 Writing:6.5 Overall:7.0 CEFR level:C1

Skills

Good Chromatographic skills and numerical skills, analytical skills, teamworking skills, team building patience, attention to detail, decisiveness, independence.

Education

04/1999 – 04/2000 Secondary. 04/2000 – 04/2002 Higher Secondary. 04/2002 – 04/2005 Bachelor of Science (Chemistry). 04/2006 – 04/2008 Master of Science (Marine Chemistry)