ISRP

DIRECTOR | SENIOR MANAGEMENT | PHARMACEUTICAL | RESEARCH & DEVELOPMENT

- Professional with over 15 years of experience dedicated to analytical development and validation.
- Solid foundation in developing and maintain quality management systems, standard operating procedures and research and development formulations.
- Well versed in designing, planning, performing and documenting scientific experimental results focused on organizational goals and maximizing targets through motivating, coaching and mentoring employees.

✓ Strategic Planning and Execution
✓ Risk Mitigation and Management
✓ Analytical Testing
✓ Client Relationship Management
✓ Compliance and Data Integrity
✓ Internal and External Audit
✓ Productivity Enhancement
✓ Training and Mentorship
✓ Project Management
✓ Reporting and Documentation

PROFESSIONAL EXPERIENCE

[redacted] PHARMACEUTICALS [redacted]

Associate Director (Head of the Department- Analytical) (June 2019-Present)

- Leadership of Analytical department operations consisting of a 54-member team.
- Manage day to day operations related to projects being developed in R&D.
- Manage department budget and capex requirement as per the allocated budget.
- Maintain high safety standards by regularly monitoring the use of appropriate PPE's while working in lab.
- Manage and solve Analytical challenges related to method issues at manufacturing sites QC in collaboration with QC.
- Periodic updates to the global management team on projects and further planning of nGMP/GMP campaign and handle Analytical method transfers at receiving sites.
- Address and plan for Deficiency letters in the stipulated time frame and support various DMF filings in different countries and supporting the global RA teams in filing.
- Deal with any issues related to Analytical methodologies raised by API Customers.
- Hiring and training of the team as per department requirements.

Senior Manager, ADL (2013-2019)

- Provided leadership to a team of 17 analytical scientists based on SOPs, GMP and HSE standards to support developmental activities for APIs, KSM, raw materials and other products.
- Coached and developed team to identify impurities using various techniques including Preparative HPLC, Flash chromatography, NMR, LCMS, GCMS, TLC-MS and other internal strategies.
- Assessed analytical data using innovative and orthogonal techniques within project and operational scope to analyze quality attributes of the product.
- Coordinated all activities related to preparation of technical documentation including preparation and presentation of reports, Genotoxic assessments and evaluation of results.
- Defined specifications for APIs, intermediates, KSM with a foundation based on evaluated key quality attributes; maintained timely follow up with support teams across locations to ensure compliance to analytical development schedules.
- Organized training sessions for analytical associates to enhance individual skill sets and create deeper understanding of quality systems, products and projected goals.
- Ensured seamless transfer of technology across multiple sites through streamlined processes and transparent communication with all departments.
- Prepared presentations containing various status reports, statistical data and forecasted projects to senior management and stakeholders to assist with strategic decision-making processes; actively participated in project meetings and presented analytical developments during development cycle.
- Ensured resolution of identified deficiencies received from various authoritative bodies including: USFDA, Canada, MHRA, PMDA, TGA and other statutory regulations.
- Managed any and all administrative duties related to analytical development of reporting data while ensuring careful attention in all submitted communication.

[redacted] DEVELOPMENT CENTRE, [redacted]

Group Expert, Analytics API – Formulation Division (Jan 2011-Jun 2011)

- Led team of 8 analytical scientists specializing in key development activities on LCMS, NMR, GC, GCMS. XRD, DSC, TGA, stability studies, wet analysis and other activities.
- Developed, planned and implemented stability studies for intermediates and APIs meeting requirements of project scope and operational targets.
- Evaluated drug safety results and collected information by conducting drug excipient compatibility study to ascertain impurity profiles generated through stability studies.
- Focused on optimization of resource usage by projecting and planning daily analytical activities with formally assigned duties to analytical team to ensure timely release of generated reports and collected statistical information.
- Prepared and presented structure elucidation reports, characterization reports to senior management and leadership teams; acted as SME on analytic results and information.
- Instrumental in the development of method activities on HPLC, GC, Preparative HPLC, Flash chromatography and LCMS.
- Planned experiments and trials for characterization of APIs, impurities and deficiencies by application of knowledge regarding NMR, LCMS, HPLC and Preparative HPLC.
- Resolved reported deficiencies from governing bodies including USFDA, TGA, MHRA, PMDA and Canada in a timely manner with long term and permanent solutions.

[redacted] BIOSCIENCES [redacted]

Scientist II – Head of Analytics (2008-2011)

- Managed analytical operations of department encompassing procurement of instruments, establishing policies and procedures, report generation, communication and all administrative duties.
- Actively participated in method development activities on HPLC, Preparative and LCMS, structure elucidation and purification tasks.
- Coordinated all activities related to set up of analytical lab and organizing training for associates on HPLC, LCMS, NMR and Preparative HPLC operations to provide support to the drug discovery department.
- Maintained, communicated and kept up to date on knowledge of routine analysis of NMR samples including Proton NMR, 13C NMR, DEPT and 2D experiments involving HSQC, HMBC, COSY, TOCSY, 1D NOE, NOESY, and other analysis.
- Continually focused on providing long term and permanent resolutions in NMR, LCMS, HPLC and Preparative HPLC dedicated to maintaining seamless implementation of project phases.

PREVIOUS ASSIGNMENTS

- **Research Scientist**, [redacted] Pune (Jun 2006 – Apr 2008)
- **Research Scientist – Analytical Research**, [redacted] (Apr 2004 – May 2006)
- **Officer**, [redacted] Biotech Research [redacted] (Jan 2002 – Apr 2004)
- **Research Chemist**, [redacted] Pharmaceuticals [redacted] (May 2001 – Jan 2002)

EDUCATION & PROFESSIONAL DEVELOPMENT

[redacted]
Master of Science in Applied Chemistry, specializing in Pharmaceutical Science (2002)

[redacted]
Bachelor of Science in Industrial Chemistry, specializing in Industrial Chemistry (1998)

Active participant in conferences on Genotoxicity, 21 CFR Part 11 requirement, Data Integrity, Space to Lead Program and currently being involved actively to implement Opex within the department.