KAUSHIK BADRI BALA
U-44 Satellite Complex
Premchandnagar Road
Satellite, Ahmedabad-380015
Gujarat, India

OBJECTIVE:
Seeking a position that matches my on-hand skills as a Quality assurance/Research and development scientist, Clinical Research Scientist / Analytical / Organic / Flavors Chemist and Industrial technologist

PERSONAL PROFILE:
Organic / industrial Chemistry / Polymer Chemistry / Clinical Research Scientist with considerable experience in the QC & QA Domain of international biotech and pharmaceutical Companies, acquainted with GLP GMP, R&D and QA / technical assurance work environments.

EDUCATION:
MS Org. Chemistry (Research) – ***Univ. of New Hampshire, NH, USA (25 May' 2016).***
MS General Chemistry - ***Montclair State University, NJ, USA (31 Aug' 2011).***
MSc Organic Chemistry- ***Gujarat University, India (15 Mar' 2005).***
BSc Organic Chemistry- ***Gujarat University, India (21 Dec' 2002).***

ACADEMIC EXPERIENCE:

University of New Hampshire (Durham, NH, USA) Aug 2012 – Feb 2016
Teaching Assistant:

- Attained good laboratory skills based on relevant degrees e.g. Wet Chemistry, Organic Separations (SPE, LLE etc), pH analysis, TGA, Volumetric & Colorimetric estimations, KF / LOD determination, Column chromatography, Spectroscopic techniques e.g. HPLC-UV / MS, GC, FTIR and NMR.
- Facilitate and attend all lectures and recitations as assigned for the purpose of being able to tutor students.
- Prepare and present pre-laboratory talks as well as prep chemicals, reagents and set up laboratory for student use. Ensuring student safety within the lab.
- Collate, distribute, proctor and grade lab assignments and examinations (formulations, quizzes, tests and reports).
- Maintain office hours at times and not in conflict with student's schedules. Tutor students as needed.
- Tally scores, prepare distribution curves and keep records of examinations, quiz and lab grades and turn it to the instructor in a timely fashion.

University of New Hampshire (Durham, NH, USA) ***April 2015 – Feb 2016***
Environmental Health and Safety (EHS) Chemist Intern:

- Managing chemical inventory using the laboratory information management system (CEMS).
- Segregating and barcoding chemicals based on hazard class and decommissioning chemicals based on state and federal regulations (EPA, DOT and IATA).
- Updating the safety data sheets / material safety data sheets and labeling waste containers (Chemical and biological).
- Placing hazard signs and placards on appropriate lab-working locations and ensuring the effectiveness of personal safety in the lab environment (OSHA).
- Maintaining the labs and updating the chemical and supplies inventory. Assisting chemists with bench chemistry and providing them safety training on a yearly basis.
- Notifying EHS of immediate working hazards and incident reports if any (OSHA).

University of New Hampshire (Durham, NH, USA) ***Mar 2015 – May 2016***
Research Assistant:

- Synthesize known compounds efficiently using literature or in-house notebook procedures.
- Synthesize new compounds by making appropriate modifications of known methods or modification of reaction conditions under minimal supervision.
- Purify synthesized chemicals to an appropriate degree using the full range of chromatographic, crystallization and distillation techniques.
- Analyze and identify compounds using a good range of modern separation and spectroscopic techniques. This will include interpretation of TLC, HPLC, polarimetry, MS, IR, and NMR spectra of moderate complexity.
- Conduct literature searches for specific target compounds, structures related to the target compound, or to determine specific conditions for compounds and reactions.
- Organize work time so that several reactions are run concurrently. Use time efficiently to produce target compounds and perform other tasks.
- Recommend and implement methods to increase the quality of products and/or services.
- Find new and better ways of performing job by challenging established procedures.
- Keep accurate, legible and complete records of all experiments and observations.
- Submit acceptable written periodic reports. Prepare summaries of experimental findings reliably and independently.
- Discuss routinely with supervisor the status of assigned programs and potential problems. .
- Communicate orally and in writing unexpected occurrences that could adversely effect established timetables.

- Managing workload and time to perform multiple projects effectively, and ensure all necessary paperwork is completed on a timely basis.
- Display the ability to assimilate previously gained knowledge and experience and apply those concepts, techniques, etc. to new and related project areas.
- Conduct laboratory operations in a safe manner. Maintain familiarity with the Chemical Hygiene Plan. Exhibit safety awareness and safe work practices.
- Follow responsible actions regarding chemical disposal. Maintain compliance with all regulations at the federal, state, and local levels.
- Volunteer to assist with tasks not directly related to specific projects.
- Practice preventive maintenance on laboratory equipment and replenish laboratory supplies as stock depletes to prevent laboratory "down-time".
- Participate in self-development activities and training of others.
- Perform other related duties as may be reasonably assigned in the course of business.

PROFESSIONAL EXPERIENCE

CloudLIMS Lab Solutions Pvt. Ltd. (Indore, India) Jul 2020 – Present
Sr. Bio-Informatics Analyst

- Analyse and document customer requirements and business processes.
- Tailor CloudLIMS LIMS solution and implement it through configuration.
- Deliver training courses to the customer project team.
- Assist customers with their validation and testing stages appropriate to their industry.
- Handling feature requests from clients through potential conversation, analysis and possible troubleshooting.
- Identifying individual industry backgrounds for clients and coaching sales personnel for their industry.
- Participation in tutorial technical reviews and industry demo guide reviews.
- Provide configuration support to sales personnel on ad-hoc basis.
- Perform competitive analysis with different software vendors.
- Providing support with delivering instrument integration and software integration (EMR, ELN) projects.
- Assist with configuring test reports, CoA's, labels and barcodes as per client specification.
- Assist in LIMS validation for clinical research and diagnostics industry.

Intervein Laboratories Pvt. Ltd. (Ahmedabad, India) Dec 2018- Jul 2020
Manager, Quality Assurance

- Planning and performing in-process, retrospective and system audits towards clinical laboratory operations
- Ensuring quality and compliance within and between clinical laboratories in accordance with CAP, ISO and NABL guidelines.

- Verification of electronic audit trail in study data using LIMS after technical review by lab director.
- Ensuring continuous supply of diagnostic kits and adequate storage of Quality controls, reagents and matrix samples
- Providing periodic reports of audit findings to the lab director in-case of system, technical and operational anomalies.
- Ensuring adherence to Corrective and Preventive action plan and filing of investigational / deviation reports in case of operational / system anomalies
- Preparation of training matrix for in-house staff and periodic updation of the quality manual.
- Preparation of Organogram.
- Document organization, data control and archiving of study related information in accordance with in house policies and regulatory guidelines
- Qualification of vendors and external laboratories by performing onsite audits.
- Periodic review of standard operating procedures and review of change request and control documents towards system implementation.
- Updating Master list of instruments and equipments and ensuring periodic review of in house SOP's in line with applicable regulatory requirements.
- Participation in management review meetings and assisting lab director with routine and walk-in regulatory inspections e.g. FDA, CAP & NABL.

Synchron Research Services Pvt. Ltd. (Ahmedabad, India) Jun 2016 – Nov 2018
Executive, Quality Control / Quality Assurance

- Planning and performing in-process, retrospective and system checks within bio-analytical operations.
- Ensuring calibration and validation of analytical instruments and equipments in a timely manner.
- Handling and resolving project / validation related issues received from sponsors and regulatory agencies.
- Reviewing and updating standard operating procedures and its adherence towards ensuring quality of the data generated, documentation of inter / intra-laboratory standardization methods and quality assurance procedures.
- Document organization, data control and archiving of study related information in accordance with in house policies after regulatory approval.
- Training in-house staff on different Quality policies, bio-analytical protocols and working instructions.
- Ensuring the receipt of test systems, working / reference standards and reagents required to initiate bio-analytical operations.
- Ensuring adherence to Corrective and Preventive action plan and filing of investigational / deviation reports in case of operational anomalies.
- Updating Master list of instruments and equipments and ensuring periodic review of in house SOP's in line with applicable regulatory requirements.

Daiichi Sankyo Pharma Development (Edison, NJ, USA) ***Sep 2011 – Dec 2011***
Consultant Records Management

- Receipt, Reconciliation, Management and Archival of Regulatory and Clinical / Bioanalytical documentation.
- Ensuring that filing structure and organization of regulatory documents within the TMF is compliant as per regulatory standards.
- Maintaining Master Inventory Tracker for Regulatory, Clinical and Bioanalytical Documents.
- Conversion, loading and verifying audit trails for Source documents / Data into electronic versions using the document management system ensuring its compliance with 21 CFR Part-11.
- Scanning of Electronic version of source documents / data into required job packs and folders ensuring its limited access ensuring compliance with in-house SOPs and regulatory requirements.

Lambda Therapeutics Research Ltd (India) ***May 2006 – Aug 2009***
Senior Research Associate QA

- Review clinical study reports and (Protocols, Standard Operating Procedures and TMFs) for ***IND / NDA submissions*** and providing QA Certification following ICH-GCP guidance.
- Providing Assistance in carrying out audits of bio availability & bio equivalence studies, Pharmacovigilance and Phase I/II/III & IV (***Post Marketing Surveillance***) clinical trials.
- Monitoring Of Spiking solution preparation & Matrix spiking (CC / QC Preparation) / ***Sample Separation / Shipment Activity*** (***Cold Chain Management***) for BA/BE as well as Clinical trial studies conducted internally and at external sites i.e. Site initiation till site close out (In Case QA services are offered to the Client).
- Monitoring of hazmat management systems and HACCP standards. Keeping abreast of EPA regulations e.g. RCRA, CAA, CWA, CERCLA, SARA etc and Trouble shooting with Lab Instrumental techniques.
- Hands on experience on ***reviewing CMC documents***, ***CTDs and e-CTDs (Modules-2-4)*** / SOPs and Pharmacological protocols and auditing the PSURs for Safety reporting (Adverse event documentation) and Clinical summary event for ***initial registration***, ***dossier preparation and submission.***
- Auditing method development,/ validation activities and subject sample analysis processing techniques and ensuring Environmental monitoring and ***safety regulations*** in the lab.
- Auditing and approval / rejection of calibration certificates of in-house instruments and equipments and ensuring traceability with NIST / NYLAP standards.
- Performing in-process, retrospective and system audits for clinical and bio analytical data, equipments and facilities. Authorizing deviations and Change controls.
- Handling and resolving Project / Method Validation Related Queries received from Sponsors and Regulatory Agencies (E6, E3 and ICH Q7, Q9 and Q10).

- Preparation and Review Of Standard Operating Procedures (SOP's) and organization / submission of dossiers based on guidelines as recommended by USFDA, CAP, AFSSAPS, EU (EMEA), TGA, MHW (JP), TPD, WHO, ISO 9001 and ANVISA.
- Auditing and Approval of Clinical data and Bio-analytical data using SDMS (Scientific date management System) software, Waters (Chromatographic Systems) and Electron data capture (EDC), Document Management System (Jar tree) and Adverse Event Reporting System (AERS).
- Maintaining. Organizing, Control, distribution and Archival of Trial related documents e.g. ICF / e-CRFs, TMF, Investigator files, Protocol and relevant SOPs.
- Auditing collection and management of Clinical and Analytical data using ***IVRS*** (***BioClinica***), its frequent validation / testing and approval of related documents from trial initiation to close out.
- Timely reconciliation and review of **annual authored and submitted** clinical / bioanalytical reports ensuring compliance with **international regulations** and proving the safety and efficacy of the investigational pharmaceutical product.
- Training the staff in Quality Assurance, Clinical & Bio-analytical SOP's, and pertinent regulatory guidelines.

Synchron Research Services Pvt. Ltd (India) ***March 2005-May 2006***
Officer, Corporate Quality Assurance

- Executing clinical trials & BA/BE studies in accordance with FDA, EU, CDSCO and ICH-GCP (E6).
- Timely evaluation and coordination of annual reviews of SOP's, updating and making them effective. Equal participation and coordination in writing new SOP's as required in due course of time.
- Tracking and archival of SOP's, validation and study related (Clinical / Bio-analytical) documents their distribution monitoring and control.
- Performing Quality control review of documents, case report forms, protocols informed consent forms, policies, procedures and reports of undertaken clinical studies
- Performing internal audits on trial and site specific master files and various others as per the local and international guidelines and regulatory requirements.
- Performing Quality control review of bio-analytical documents e.g. meta data and chromatograms, Bio-analytical study / validation protocols and final analytical study report (i.e. Volume-II) of undertaken Bio-analytical studies
- Evaluating and taking Corrective and Preventive action on the basis of feedback.
- Participating, developing and implementing a comprehensive and standardized Quality Management plan for the organization.
- Collecting , updating and communicating various local and international regulations and guidelines important information among various departments
- Preparation of SOP's, assurance of the quality of the data, documentation of inter-laboratory standardization methods and quality assurance procedures
- ***Document organization and Data control***, Archiving Of Reports / Raw Data / Other Study Related Data.

- Conducting Vendor Audits.
- Training to staff in Quality Assurance, Clinical & Bio-analytical SOP's

Claris Life sciences Ltd, A' bad, Gujarat (India) ***Aug 2004-March 2005***
Officer, In-process Quality Assurance Dept.

- Supervision of in process quality operations of manufacturing systems, Dispensing operations, Line clearance of products under manufacture at various levels.
- Tracking manufacture, Sampling, supply and use of correct starting ***Raw materials and packing materials*** and ensuring their placement in respective quarantine zones.
- Ensuring the safety of the drug substance / product by auditing data generated through stability and analytical studies e.g. dissolution testing (release and shelf life), validations (method / process), environmental monitoring results (bacterial and viral counts) and impurity profiling (residuals, metabolites etc).
- Planning and conducting Vendor audits for raw material supplies, CMOs, Contractual Labs and In-process, Retrospective and System audits for in house cGMP operations.
- Reviewing and approving / Rejecting (Holding) product and package labels (***labeling***) and performing in-process audits for production / manufacturing activities as per 21 CFR 201.
- Reviewing Drug manufacturing and packaging records prior to and during production initiation and approving System and Process based SOPs / Protocols, Process / System Validation dockets for instruments and equipments qualification.
- Customer complaint, query handling and performing Pre-Approval Inspections. ***Identifying gaps*** within the system and ensuring corrective and preventive actions for deviations pertaining to the system and process specific SOPs and cGMPs
- Participation within in-house and external environmental quality control schemes. Organize and complete shipments of internal and external project documents and related data to the Client.
- Ensuring Safety procedures within the facility, manufacturing units and respective clean rooms. Training in house staff and external agencies on SOPs and current regulatory practices.
- Maintaining Business History files (BHFs) and ensuring relevant supplies and APIs to be released to various clinical and manufacturing sites and relevant documentation archived after study completion (***Inventories and Lab notebooks***).
- Approval of Batch manufacturing and batch packaging records and providing product release after necessary product review cycle (APR) and sterility transfers.
- Officer for in-process quality assurance dept. carried out audits in collaboration with other MHRA, ISO 9001 (2008) / 17025 and USFDA accredited organizations.

COMPUTER SKILLS:

Programming: Microsoft Office, C, C++ and JAVA. **Advanced computational skills:** *Applications (Computational Chemistry):* SPARTAN interface Versions: Student-6, 10, 14 and Gaussian and Cylview.

RESEARCH AREAS:

1. *Studies on thermodynamics of carbon-dioxide resulting the outgassing of Lake Nyos*. **(Spring-2010)**.
2. *Zinc carbenoid-mediated homologation-cyclopropanation within β-keto substrates and selectivity within cyclopropanoxide rearrangements* **(Fall-2012)**.
3. *Zinc carbenoid mediated homologation of α-carboxyester imides and synthesis of substituted γ-butyrolactones as derivatives of paraconic acids.* **(Spring-2014)**.

PUBLICATIONS:

1. Bala.K.; Zercher. C.K. "I. Zinc-mediated homologation-cyclopropanation in β-diketones and selectivity within cyclopropanoxide rearrangements. II. Zinc mediated tandem chain extension-aldol reaction and formation of substituted γ-lactones", *University of New Hampshire, ProQuest Dissertations Publishing*, **2016**, 10127312.