RESUME

Hiral Soni

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OBJECTIVE:

Seeking a position where my knowledge and skills can be utilized to fulfill the organization's goals.

SUMMARY:

- Educationally qualified with M.Phil (Microbiology), M.Sc (Microbiology) and PGDACR (Post Graduate Diploma in Advance Clinical Research) from Gujarat University, Ahmedabad. Certified Microbiologist from American Society for Clinical Pathology, board of registry number-5238.
- Knowledge of ICH-GCP, NDCT rules 2019, GLP, GMP. Trained on Quality standards like ISO 9001, ISO 17025 and ISO 15189 and NABL 112.
- Handled regulatory audits such as Indian FDA, accreditation audits such as WHO-GMP, ISO 9001, ISO 15189, ISO 17025, American Association of Blood Bank (AABB).
- Result oriented, solution driven, good interpersonal, written and verbal communication skills.

PROFESSIONAL EXPERIENCE:

1. **Avron Hospitals Pvt. Ltd., Ahmedabad** **March'19 to March'20**
   Assistant Manager-Clinical Research

- Responsible for development of clinical research department through meeting with sponsors, investigators, SMOs for new studies.
- Responsible for reviewing Clinical Trial Agreement, provided feedback for any changes or amendments and finalized the agreement.
- Assisted the investigator in conducting the study as per the standard operating procedures (SOP), regulations and good clinical practice (GCP) guidelines.
- Reviewed patient data and identify potential patients for the study.

- Helped the investigator in screening patients.
- Assisted investigators in the Informed Consent Process, coordinating and managing laboratory samples, and follow-up of lab reports.
- Ensured proper investigational product accountability, management, dispensing and temperature monitoring at the site.
- Ensured compliance of project specific schedule of activities. Ensured study related proper documentation.
- Ensure compliance of SOPs.
- Responsible for site audits, site qualification visits, site initiation visits, monitoring visits and resolving queries within a stipulated timeline.
- Responsible for ensuring timely entry of data into eCRF database (Medidata Rave) accurately and source document verification.
- Responsible for AE/SAE management.
- Responsible for patient travel reimbursement.
- Responsible for tracking site payment milestones and published timely invoice to accounts department.
- Responsible for preparing site for bioequivalence studies.
- Functioned as institutional ethics committee coordinator for other studies. Collected, reviewed and submitted study documents for ethics committee review, scheduled EC meetings, prepared minutes of EC meeting. Obtained EC approval letter. Maintained and updated EC SOP and other EC documents as and when required.
- Completed course on Good Clinical Practice from NIDA Clinical Trials Network.

2. Ethicare, Ahmedabad **Jan'17 to Nov'18**

Group Leader

- Conducted site feasibility, site initiation, site interim monitoring and site close out visits for pharmacokinetic studies and monitored clinical phases, clinical close out, bioanalytical In-process, bioanalytical close out, for bioequivalence studies.
- Performed quality checks of clinical data by verifying data of paper CRF and data entered in the software system.
- Reviewed Trial Master File.
- Prepared and reviewed monitoring and clinical study reports.
- Prepared compliance verification responses for study monitoring reports.

- Responsible for communication with sponsor, site or CRO for project status, scheduling of monitoring visits or for any other project related queries.
- Responsible for registration of clinical trials on Clinical Trial Registry of India (CTRI) website.
- Managed regulatory authority applications for investigational new drug and medical device for different countries, prepare regulatory dossier as per regulatory guidelines, submission of regulatory dossier to DCGI for trial approval and prepared responses for regulatory queries raised.
- Reviewed Institutional Ethics Committee (IEC) dossier for submission to sites.
- Formed Institutional Ethics Committee for clients as per ICMR guideline and Schedule Y.
- Helped in preparing pharmacovigilance system for clients.
- Prepared training agenda and gave training to employees.

2. SGS India Pvt. Ltd., Ahmedabad March'16 to Jan'17

Quality Assurance Manager

- Performed quality management functions like review of SOPs/forms, Corrective actions/preventive actions, root cause analysis, handling of deviations, training, conducting management review meetings, handling customer complaints, documentation and maintenance of quality records and preparation for NABL, APEDA accreditations.

3. StemCyte India Therapeutics Pvt. Ltd., Gandhinagar Oct'11 to Nov '15

QA/QC and Compliance Manager, Transplant coordinator

- Coordinated transplants and clinical trials for treating patients using UCB stem cells.
- Created, implemented and managed quality management system all through the department and organization to ensure quality maintenance and continual development.
- Implemented policies and procedures in various departments and responsible for archival of expired documents.
- Prepared quality manual, site master plan, biosafety manual, annual product quality review report and evaluated effectiveness of quality assurance program to ensure product safety and efficacy.

- Investigated non-conformances trends by performing internal audits (in-process and retrospective audit of raw data) and developed root cause analysis, corrective actions/preventive actions/risk analysis (CAPAs), deviation handling and ongoing internal audit plans for continual improvement.
- Performed trend analysis of various quality metrics, evaluated quality outcome and prepared and presented quality assessment reports in management review meetings.
- Performed vendor/supplier qualifications and performance review, conducted vendor site audits. Implemented procedures for change control, product stability studies, validations, environmental monitoring and gave training.
- Responsible for acquiring and maintaining national and international accreditations such as ISO 9001, NABL, WHO-GMP, AABB and state FDA license.

4. Diagnostic Lab, USA **April'06 to Dec'10**

Microbiologist

- Performed hematology, coagulation, serology, IFA, bacteriology, mycology, virology and molecular testing.
- Perform quality control and proficiency testing.

5. Lambda Therapeutics Research Ltd., Ahmedabad **Oct'04 – March'06**

Clinical Research Associate

- Involved in project coordination, proper initiation and timely conduct of bioequivalence and bioavailability studies as per ICH-GCP guidelines, protocol, SOP and applicable regulatory authorities.
- Reviewed study related documents, maintained clinical research data and accurately completed study documentation of source documents, case report forms.
- Documented, monitored and reported adverse events in timely manner and sent clinical updates to study sponsor and EC.
- Prepared clinical side of report.
- Managed subject follow up for unresolved adverse events, compensation, coordinated and resolved QA queries in timely manner, updated various forms, logs and SOPs in the department.

PROFESSIONAL TRAINING/CONFERENCES ATTENDED:

- Indian Society for Clinical Research (ISCR) conference on "Clinical Research Landscape-Post 2020", 09-10 October, 2020.
- Conference on "Regional and multi-regional clinical trial (MRCT) from global regulatory perspective", organized by Basilion Research on 11th May 2019.
- Training on Laboratory Management and Internal Audit as per ISO 17025 conducted by Standardisation Testing and Quality Certification Directorate, Government of India, Date: 8th august-11th august, 2016.
- Training on Quality Management System Auditor course as per ISO 9001 from Bureau Veritas. Date: 21st Oct, 2013.
- Training on Internal Audit and Quality Management System as per ISO 15189 and NABL 112 from Quality Council of India, Date: 24th-27th April, 2013.

EDUCATION:

- Post Graduate Diploma in Advance Clinical Research, Gujarat University, Ahmedabad, year May-2021, result- First class with distinction
- Master of Philosophy, Microbiology from School of Sciences, Gujarat University, Ahmedabad, year Oct-2006, result- First class.
- Master of Science, Microbiology from School of Sciences, Gujarat University, Ahmedabad, year May-2003, result- Higher second class.
- Bachelor of Science, Microbiology from Gujarat University, Ahmedabad, year May-2001, result- First class.
- Certified Microbiologist from American Society for Clinical Pathology-M(ASCP)CM USA, certification no. 5238.
- **Research Paper Publication:** Effect of different microbial treatments on seedling development of ***Trigonella Foenum***. In Journal of microbial world, vol 9 no.2, 223-228, 2007.

SOFTWARE SKILLS:

- MS Word, MS Excel, MS PowerPoint, MS Outlook, Octalsoft Clinical Trial Data Management Software System, Laboratory Information System, scientific literature search, internet browsing.