CURRICULUM VITAE

Name : Rukma K. Rana
Phone Number : (M) +91 9727502433
Email ID : rukmagandhi1997@gmail.com
Register Pharmacist no. : G/67782

CAREER OBJECTIVE:

Looking to use my experience in clinical research field along with my expertise in leadership & organizational skills & combine it with my inclination towards learning new things which will further my career growth & also help me to lead & motivate my team members & boost the profitability of company.

PROFESSIONAL EXPERIENCE

1. Jr. Clinical Research Associate- Mar 2021 to present at CRO-CBCC Global Research Pvt Ltd, Ahmedabad
2. Site Clinical Research Coordinator: Sterling hospital, Vadodara (Oct -2020 to Mar-2021)

CLINICAL TRIAL EXPERIENCE:

As a Jr.CRA:-

Bioequivalence, US FDA Submission, Multicenter, National with indication: **Advanced Renal Cell carcinoma (Pivotal Study)**

Relative bioavailability, US FDA Submission, Multicenter, National with indication: **Advanced Renal Cell carcinoma (Pilot Study)**

As a site CRC:-

Phase 3, US FDA Submission, Multicenter, Global with indication: **Moderately to Severely Active Crohn's Disease.**

Long-Term Extension Study, US FDA Submission, Multicenter, Global with indication: **Ulcerative Colitis.**

JOB PROFILE:

As a Jr.CRA

- ✓ Identification and development of robust Site/Investigator Database for different indications
- ✓ To perform Project specific site level feasibility assessment
- ✓ To shortlist the sites from the in house database where the feasibility assessment was performed
- ✓ To collect study documents (IU/PSP/CV/FDA 1572 etc.) from site for regulatory submission
- ✓ To collect documents from sites for EC submission
- ✓ To prepare and dispatch the EC Dossier to Site for EC submission in consultation with CRA/PM.
- ✓ To prepare and dispatch the DCGI Dossier to DCGI liaison person for DCGI submission in consultation with CRA/PM or To assist PM for online DCGI application
- ✓ EC & DCGI submission and approval tracking
- ✓ Project specific Clinical trial supply to the site like ISF, PF, and PK kits, Central Lab kits etc.
- ✓ To finalize the material, Coordinate with vendors and to send the Cards/keychain/posters for exclusion/

inclusion to sites

- ✓ To assist PM for getting the Site agreements executed
- ✓ Prepares site files, trial master files, trial related trackers, draft communications etc.
- ✓ Ensures the study startup related activity tracking and reporting to PM
- ✓ Review the TMF periodically for the completeness and follow up with CRA and/or PM for any open action items.
- ✓ Resolve the QA audit findings in consultation with CRA/PM.
- ✓ Assist PM for the weekly/monthly project status report
- ✓ Ensures compliance with the Quality Standard requirements of quality management system and relevant documentation.
- ✓ Other duties as assigned by CRA, PM, Head-PM and DO.
- ✓ To work as per GCP, New Drugs and Clinical Trials Rules, 2019 and to Ensure Compliance for the same.

As a Site CRC:

- ✓ Ensuring the conduct of the Clinical Trials as per ICH-GCP & Protocol specified guidelines.
- ✓ Assist in Process of administering the informed consent to potential patients and discussing in detail the patient information sheet.
- ✓ Performing IWRS, study drug accountability and Dispense study medication & Writing source document.
- ✓ Completion of Electronic Data Capture (EDC) and paper Case report Forms (CRF).
- ✓ Collaboration with CRA
- ✓ Schedule subject visits as per protocol to ensure maximal subject compliance retention.
- ✓ Submission of documents and Notification of CIOMS
- ✓ IP Management- Storage & Accountability
- ✓ To prepare documentation for submission, review and approval by the Ethics Committee.
- ✓ Shipment of clinical specimens to central laboratory
- ✓ Assisting PI during the informed consent process
- ✓ Recruit and screen study participations, coordinate their clinical treatment and follow up care, and help facilitate their continued participation.
- ✓ Collect, submit and maintain study data and regulatory documents.
- ✓ To solve EDC Query within timelines
- ✓ To coordinate with Investigator & solve their queries.
- ✓ Maintain all documents in investigational trial files
- ✓ Coordinating for the calibrations of all the instruments.

EDUCATIONAL BACKGROUND:

- ➢ 2020: M.Pharm (Pharmaceutics) from Gujarat technological University at Sardar Patel College of Pharmacy, Bakrol.
- ➢ 2018: B.Pharm from Gujarat technological University at Sardar Patel College of Pharmacy, Bakrol.
- ➢ 2014: 12th Standard from GSEB, Gandhinagar, Gujarat, India.
  2012: 10th Standard from GSEB, Gandhinagar, Gujarat, India.

Practical Training Experience:

Complete one month of training at SIDMAK pharmaceuticals,Valsad.

SKILLS SET:

Interpersonal skills:

Adaptability, Problem solving and analytical skills, good communication skills, Time management, Willingness to learn, Dedication to work, Patience, Well Organized.

Technical skills:

» Instrument: Tablet Punching Machine, Dissolution apparatus, Disintegration apparatus, UV apparatus, Roche Friabilator.

» Operating System: Proficient in Computer along with EDC software (MEDIDATA RAVE,Clinion), Windows XP/07/08/10 Microsoft Office [MS Word, MS Power Point,MS Excel,MS Publisher]

PERSONAL DETAILS:

Name	Rana Rukma K.
Date of Birth	January 02,1997
Address	113,Pritam Society no.-2, Near G.E. Board, Zadeshwar road, Bharuch-392002
Nationality	Indian
Gender	Female
Languages known	Gujarati, Hindi and English

DECLARATION:

I solemnly declare that all the above information is correct to the best of my knowledge and belief.

Date:

Rana Rukma K.