CURRICULUM VITAE

1. PROFESSIONAL EXPERIENCE

Organization and Duration	Job Responsibilities
COD Research Pvt. Ltd., Ahmedabad, India. (13 Dec 2021 to till date)	**Functional Designation : Sr. Executive** **Involved in as a: CRA** • Perform site-monitoring visits (selection, initiation, monitoring and closeout visits) in accordance with contracted scope of work and regulatory requirements, i.e., Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines. • Work with sites to adapt, drive, and track subject recruitment plan in line with project needs to enhance predictability. • Administer protocol, related study training to assigned sites, and establish regular lines of communication with sites to manage ongoing project expectations and issues. • Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate. • Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrolment, case report form (CRF) completion and submission, and data query generation and resolution. May support start-up phase. • Ensure copies/originals (as required) site documents are available for filing in the Trial Master File (TMF) and verify that the Investigator's Site File (ISF) is maintained in accordance with GCP / ICH and local regulatory requirements • Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation. • Act as a mentor for clinical staff including conducting co-monitoring and training visits with CRAs. • Assist in selection of the sites in conjunction with sponsor and COD Research Pvt. Ltd. and recommend site assignments. • Supports the Clinical Research Associates (CRAs) with site monitoring activities and provides suggestions and solutions to site issues where applicable. • Coordinate end-to-end cross-functional project operations and multi-disciplinary activities to ensure that project deliverables are met • Monitor progress of project activities and deliver frequent updates to the Project Leader and Team

	• Involved in coordination with legal team to prepare and review and/or to execute agreements with investigators and vendors (Master service and/or amendment, CDA, NDA) • Collaborate and liaise with study team members for project execution support as appropriate. • If applicable, may be accountable for supporting development of project subject recruitment plan on a per site basis • If applicable, may be accountable for site financial management according to executed clinical trial agreement and retrieve invoices according to local requirement. • Identify and screen newer sites and PIs. • Responsible for maintenance of CTSM facility including temperature recording as per the Standard Operating Procedures (SOPs). • Responsible for receipt, storage and maintaining accountability of Investigational Product (IP) and other clinical study supplies as per the SOPs. • Responsible for IP and study supply shipment to investigational sites. • Responsible for coordination of study supply shipment activities with vendor and investigational site in consultation with project team. • Responsible for coordination of return/destruction/reorder of study supply as per SOP in consultation with project team. • Responsible for calibration/maintenance of instruments/equipment of CTSM facility. • Responsible for handling complaints received for study supply shipment. • Maintenance of study tracker and updates as per the study requirements and provide the updates to the Project Manager. • Responsible for receipt and maintenance of un-blinding envelopes at CTSM facility as per instruction from sponsor. • Any other responsibility assign by HOD/Project manager
Alkem research Centre 14 Sep 2017 to 10 Dec 2021	**Department:** Clinical **Designation:** Sr. Scientist • To develop site selection criteria basing on study specific requirements of the project. • Identifying potential PI & sites by reviewing PI's current CV, medical licensure, prior history with CI and site, site feasibility questionnaire and request for proposal • Review of all the documents and monitoring tools as needed which may include final, current protocol and current IB. • Ensuring study supplies and IP delivered to the site prior to SIV. • Ensure testing or calibration of study equipment is complete prior to SIV. • Monitors all types of clinical trials. • Study monitoring and audit of CRO

	• Preparation of Protocol synopsis, Review and Finalization of study protocol • Study Monitoring and Audit of CRO for clinical trial studies • Review of Clinical Study Report • Coordination with CRO • Preparation of clinical and non-clinical Overview • Hand on expertise with international regulatory submission, eCTD review,CDISC, ICH E-3, US FDA, EMEA, WHO and ANVISA format for Efficacy Working knowledge of Dossier Management System • Investigational Product Management (Test/Reference) • Coordinate with manufacturing units, R & D, CRCs and arrange investigational product and trial materials.
Ajanta Pharma Ltd from Feb 2017 to Aug 2017	**Department:** Regulatory affairs **Designation:** Sr. Research Officer • Actively involved in coordination and execution of trials . • My work involves ensurance of project coordination of trials as per protocol and defined SOP's by the organization; work in close coordination with the PI/Sub investigator • Monitoring and execution of trials. • Communication with the Independent Ethical Committee (IEC) and Sponsor regarding the project and related issues such Investigational Medicinal Products (IMP), Adverse Events (AE), Serious Adverse Events (SAE), discontinuation of subjects. • Ability to work independently, as well as part of a project team. • Communication with analytical and bioanalytical and R & D team.
Reliance Life science from 28 Aug 2015 to Jan 2017	**Department:** Clinical **Designation:** Sr. Executive • To develop site selection criteria basing on study specific requirements of the project. • Identifying potential PI & sites by reviewing PI's current CV, medical licensure, prior history with CI and site, site feasibility questionnaire and request for proposal • Review of all the documents and monitoring tools as needed which may include final, current protocol and current IB. • Ensuring study supplies and IP delivered to the site prior to SIV. • Ensure testing or calibration of study equipment is complete prior to SIV. • Monitors all types of clinical trials. • Participates in all types of site visits and report preparation and On site source data verification • Assures Principal Investigator (PI) integrity. • Assures compliance with all protocol requirements. • Assures effective patient identification and recruitment plan is in place. • Assures timely reporting of AEs/ SAEs and Protocol Violations.

	• Regularly performs Investigational Product (IP) accountability. • Regularly reviews the status of contents of the site Regulatory Binder. • Resolves problematic issues in a productive way. • Review all regulatory files for completeness. • Complete the verification of data in CRFs with source Documentation.
Alkem Research Centre from 01 JUN 2012 to 24 Aug 2015	**Department:** Clinical **Designation:** Research Associate • Correspondence with sponsor, IEC, Internal departments for trials related activities like designing of protocol, protocol approval, trial update, investigational products related issues, subject's safety related issues along with the Principal Investigator / Head-Clinical Operation Reviewing clinical study reports, • To prepare DBE table FDA Expert report, • Suitable planning and technical conduct regarding logistic set up of the studies for smooth operation, • Ensure conduct of the study as per the standards laid down in the SOPs. • Ensure timely conduct of clinical trials and comply with GCP guidelines, SOPs and applicable regulatory. • Monitoring and reporting of trial related activities. • Reviewed regulatory documents according to ICH/GCP guidelines. • Ensure conduct of the study as per the standards laid down in the SOPs. • Ensure timely conduct of clinical trials and comply with GCP guidelines, SOPs and applicable regulatory. • Ability to work independently, as well as part of a project team • Coordination of QA Audits of corrected forms. • To ensure subject contact during the wash-out period and follow ups. • Preparation of Case Report Forms for Bioavailability / Bioequivalence study and clinical trials. • Preparation of clinical report as per applicable regulatory guidelines • Safety reporting, Schedule the follow up visits for all enrolled subject • Knowledge of ICH GCP guideline • Preparation and Review of clinical study documents: • Coordinating with translation agency • To arrange study drugs and materials and to check its accountability and storage conditions • Follow up with sites for essential documents such as CV's, Investigator Undertaking, Ethics Committee (EC) SOPs, etc. • Trial Master File (TMF). • Preparation and review of Ethics Committee document. • Follow-up with for source data, CRF completion EC submissions/notifications. • Maintaining sponsors Trial Master File (TMF) throughout study period.

	• Coordinating with site and in house for study documents and archival process. • Preparation and review of SOP's • Handling Laboratory Information Management Software (LIMS Software-
Lambda Therapeutic Research CENTRE from 14 APR 2010 to 28 MAY 2012	**Department:** CPMA **Designation:** Project Coordinador • Actively involved in coordination and execution of BA/BE trials on healthy subject. • My work involves ensurance of project coordination of BA/BE trials as per protocol and defined SOP's by the organization; work in close coordination with the PI/Sub investigator • Monitoring and execution of Bioequivalence trials. • Communication with the Independent Ethical Committee (IEC) and Sponsor regarding the project and related issues such Investigational Medicinal Products (IMP), Adverse Events (AE), Serious Adverse Events (SAE), discontinuation of subjects. • Ability to work independently, as well as part of a project team.

2. EDUCATIONAL QUALIFICATION AND CERTIFICATION

Sr. No.	Year	Degree	University	Grade
01.	2005-2008	B.PHARMA	R.G.P.V BHOPAL UNIVERSITY	69.92%
02.	2008-2010	M.PHARMA	R.U.H.S JAIPUR	64.28%

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3. SCIENTIFIC CONFERENCE, WORKSHOPS & TRAINING

Jun 2010	Attended ICH GCP training at Lambda Therapeutic Research Limited. , Ahmedabad
Jul 2013	Attended ICH GCP training at Alkem Research Centre, Mumbai
Oct 2015	Attended ICH GCP training at Reliance life science Mumbai.
Nov 2016	Attended ICH GCP training at Reliance life science Mumbai.
Apr 2019	Attended ICH GCP training at Alkem Research Centre, Mumbai
Apr 2020	Attended ICH GCP training at Alkem Research Centre, Mumbai
Apr 2021	Attended ICH GCP training at Alkem Research Centre, Mumbai

4. MISCELLANEOUS

Personal	**Gender :** Male **Marital Status:** Married **Nationality:** Indian **Languages Known:** English, Hindi **Mail id:** naveensrcp@gmail.com **Contact no.: 9029628436,8169812856**