Position: Clinical Research Associate, Clinical Trial Management

General Responsibilities:

- This role will require the individual assume site management, feasibilities, internal and external monitoring responsibilities for single centre and multi-centre studies.
- Monitor single/multi-centre trials, Phase I – IV studies as assigned, ensuring the trial is run according to ICH-GCP, applicable Regulatory requirements, study protocol and either Sponsor or Cliantha Research SOPs.
- Perform site identification, feasibility and conduct site qualifying visits to assess the suitability of investigator and site by ensuring the investigator has the staff, time, patient population and facility to complete the study successfully, according to GCP and Regulatory requirements.
- Conduct study initiation visits to review all study procedures with the investigative team and to ensure expectations of study is understood.
- Conduct routine monitoring for single/multi-centre trials, to verify rights, safety and well being of patients are protected, ensure accuracy of study data and that the study is conducted according to the protocol, GCP and Regulatory requirements.
- Conduct study closeout visits to ensure all essential documents are in appropriate files, to ensure investigator understands ongoing responsibilities and remove all relevant study materials from the site
- Ensure that all visits are conducted according to FDA regulations and ICH guidelines, company or client Standard Operating Procedures (SOPs), as defined by the contract and/or monitoring plan established for the trial
- Prepare protocol specific training and regular updates to CRAs and other company staff
- Assist Project Associate with the collection of regulatory documents required for drug shipment clearance, as required
- Review/ file regulatory documents as required during routine monitoring and audits, ensuring investigator files (ISF) are accurate, current and identical to Trial MasterFile
- Communicate with the study site personnel and study team members as appropriate and maintain a good rapport with each
- Provide Director, Clinical Trial Management, and/or Lead CRA with monitoring reports of activities and elevate site or study issues
- Track all time and expenses and submit in a timely manner
- Ensure compliance with appropriate Cliantha Research SOP's, Regulatory and ICH-GCP regulations
- Participate and /or conduct training sessions, Participate in project team meetings as required
- Assist project Manager in developing study timelines and study conduct plans and assist the CTM team in the study start up, conduct and close out
- Provide input into development of protocols and CRFs, participate in client BID defenses

- Use appropriate communication to maintain contact with clients to ensure they receive accurate and current information on the status of their project(s)
- Assist the Project Manager or Lead CRA in tracking meetings with Operations teams to ensure milestones are on track, discuss study progress, facilitate resolution of issues etc.
- Maintain a good understanding of regulatory guidelines (TPD, FDA, EMEA)
- Ensure compliance with appropriate Company SOP's GCP and ICH guidelines

Supervisory Responsibilities:

- This position has no supervisory responsibilities

Positions Directly Supervised:

- This position has no direct report responsibilities

Qualifications:

- University Degree in Life Sciences or equivalent
- > 2 years experience in monitoring multi-centre clinical trials within the pharmaceutical industry or equivalent experience as a Clinical Research Coordinator
- Demonstrated proficiency in MS Office Suite (Word, Excel and PowerPoint)
- Decisive, good decision making skills, able to escalate response to situations when relevant
- Good analytical and problem solving skills
- Very organized and able to multi-task
- Strong analytical and problem solving skills
- Excellent organizational skills, detail oriented, efficient and able to multi-task/prioritize
- Excellent interpersonal skills, solid conflict resolution skills
- Strong written and verbal communication skills

Interested candidates can send their resume at akaler@cliantha.com