Job Description

Designation/Role: Clinical Research Coordinator (CRC) II

Department: Clinical Operations

Job Description / Roles and Responsibilities for Job Title:

1) Independently supervise and Lead the overall coordination and management of clinical studies/ Clinical study staff for BE and Phase 1-4 studies including but not limited to:

i. Recruitment, screening, and coordination of patient visits as per study protocols
ii. Execution of all aspects of study visits as experience and training allow
iii. Perform clinical and study procedures as per study protocols, ensuring minimal deviations and proper tracking and reporting when deviations occur
iv. Interact with Principal Investigator, sponsor, manager and Scientific Director and other study coordinators to ensure all aspects of protocols and study requirements are understood
v. Design, implementation and coordination of all aspects of data collection, source documentation and CRF transcription as per protocol, SOPs and ICH/GCP guidelines
vi. Data entry
vii. Participate in development and execution of Quality Control processes
viii. Prepare for and support QA audits and sponsor monitoring visits
ix. Study drug management
x. Lab Sample processing, labelling, storage, shipment, documentation and record keeping
xi. IRBs interactions
xii. Site Regulatory Documentation collection and management
xiii. Archiving
xiv. Work with study managers and other members of the study teams to ensure study performance meets or exceeds client expectations
xv. Participate in Operational kick-off meetings and regular study update meetings
xvi. Ensure study subjects are having the best possible experience while participating in studies

2) Participate in development of department SOPs, Equipment Binders, templates
3) Procurement of equipment and supplies as required
4) Calibration and maintenance of equipment per SOPs; Maintain appropriate logbooks
5) Participate in training of staff as experience and qualifications permit
6) Participate in Environmental Chamber validations and maintenance; write validation protocols and reports, conduct validation experiments, maintain appropriate logbooks
7) Assist in all aspects of company start up activities as required
8) Uphold the company mission statement and conduct yourself at all times in a respectful and business-like manner. Be a positive role model for all staff and interact with colleagues in a collaborative way
9) Assist in set up and maintenance of laboratory and EMS system
10) Execute other duties as may be required

Any Additional responsibility given by Head of the Department / Management

Qualifications:

- B.Sc., post-secondary diploma in scientific, healthcare or pharmaceutical field, or equivalent experience and/or education.
- Minimum 3 years' experience in a clinical research environment preferably including BE and Ph 1 – IV studies, EEC is desirable
- Strong analytical and problem solving skills
- Demonstrated superior leadership skills
- Excellent organizational skills, detail oriented, efficient and able to multi-task and prioritize effectively
- Excellent interpersonal skills
- Strong written and verbal communication skills
- Good trouble-shooting and decision making skills, able to escalate response to situations when relevant
- Proven solid project planning/ coordination/ management skills

The resumes can be submitted to HRMississauga@cliantha.com