Clinical Research Associate

ABOUT US
HepQuant, LLC is a clinical-stage liver diagnostics company with unique, patented and patent-pending technology for assessing liver function of patients with chronic liver disease. HepQuant technologies, have been advanced with the intent to profoundly impact the liver disease landscape – including the research, treatment and patient communities – with diagnostic products that are accurate and minimally invasive. HepQuant is focused on becoming the gold standard for measuring liver health across the full spectrum of disease severity in a cost effective and minimally invasive way to patients across the globe.

GENERAL PURPOSE OF THE JOB:
Responsible for supporting clinical research sites and assessing compliance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH) and International Organization for Standardization (ISO) guidelines, federal regulations, SOPs, and study protocols.

REPORTS TO: Manager of Clinical Trials

PRIMARY DUTIES AND RESPONSIBILITIES:
- Assist in project planning; timeline creation, preparation and review of study plans, including the Clinical Monitoring Plan and review of eCRF guidelines/specifications.
- Provide vendor management that may include EDC, IRT, Central Lab and specialty vendors.
- Develop clinical documents including ICFs, protocol support documents, Pharmacy Manuals, Lab Manuals, site support documents, source documents, and eCRF forms.
- Assess potential study sites to ensure the facility, staff and patient population are adequate for study conduct.
- Facilitate budget planning and support site budget review, tracking and reconciling site related invoices of planned vs. actual spending.
- Independently manage study tracking, enrollment, site performance
- Perform TMF reviews for assigned study(ies)
- Monitor study progress to assure compliance with protocol requirements, FDA regulations and Good Clinical Practice by conducting site visits or remote assessments.
- Perform and document monitoring assessments (PSV through closeout) as needed, and review monitoring assessments
- Ensure the timely, accurate and complete collection and submission of study data.
- Identify, address, and resolve issues and problems as they might occur.
- Ensure collection of all data and remaining study supplies for return as appropriate.
- Demonstrate strong knowledge of Good Clinical Practice/ICH Guidelines and other applicable regulatory requirements.
- Work independently in a fast-paced environment

SECONDARY DUTIES AND RESPONSIBILITIES:

- Provides support as needed to other departments
- Demonstrates the HepQuant culture
- Reports any problems / issues promptly
- Attends necessary meetings
- Performs other duties as assigned

QUALIFICATIONS:
Bachelor's degree in a relevant biological or health science discipline or equivalent experience required. An MS or relevant experience is preferred. This position requires prior clinical research experience as a working CRA or equivalent in a pharmaceutical or medical device environment. Experience should include direct study oversight responsibility as well as field monitoring. Experience as a Study Coordinator or Research Nurse in cardiovascular disease will be considered a strong plus. Familiarity with electronic case report form tools (e.g. redcap) is desired.

ESSENTIAL BEHAVIORS, SKILLS, AND ATTITUDES REQUIRED FOR SUCCESS IN THIS POSITION:

- Commitment to HepQuant Vision and Values
- Hands-on work; ability to compile own reports, studies, data
- Proven ability to work collaboratively with colleagues, and teammates to create a results-driven, team-oriented environment
- Excellent written, verbal, and interpersonal communication skills with an acute ability to listen attentively and to communicate effectively throughout all levels of the organization
- Professional demeanor and ability to interact with all personnel
- Ability to function as a strong member of a highly motivated and integrated management team
- Must live in or around the Denver area or be willing to relocate to the Denver area as this position is not remote

WORK ENVIRONMENT & PHYSICAL DEMANDS:
The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. The physical demands described below are representative of those that must be met by an employee to successfully perform the essential functions of this job.

The employee must occasionally lift and/or move up to 25 pounds (lifting boxes, files, etc.). Specific vision abilities required by this job include close vision, color differentiation, distance vision, peripheral vision, depth perception and ability to adjust focus. While performing the duties of this job, the employee is required to stand; walk and talk, and hear. The employee is frequently required to use hands to finger, handle, or feel and reach with hands.

STATUS: Full-Time
ANNUAL SALARY RANGE: $80,000-$110,000 based on qualifications
FLSA STATUS: Exempt

LOCATION: Denver, CO

BENEFITS: Include Medical, Dental, Vision, Short and Long-Term Disability and AD&D, Life Insurance, 401(k) with company match, profit sharing program.