AMAREX JOB DESCRIPTION

Position Title: Clinical Lead (CL)	Department: Clinical
Reporting Requirements: Reports to the Clinical Department Head or other supervisor as assigned	**Travel Requirements: < 10%**

POSITION SUMMARY

The Clinical Lead (CL) performs monitoring visits to ensure compliance with protocol, International Council for Harmonisation guideline for Good Clinical Practice (ICH- GCP), local regulations, applicable Standard Operating Procedures (SOPs) and project-specific requirements.

Key Duties and Responsibilities:

- Possess detailed and current knowledge of the study protocol, site monitoring plan, study manuals, GCP guidelines and Code of Federal Regulations and local country regulatory requirements
- Independently oversee and manage multiple sites within one or more protocols to assure compliance with protocols, project plans, and GCP guidelines
- Conduct on-site visits as required; pre-study, initiation, interim, and closeout visits and prepare visit reports
- Complete and submit monitoring reports
- File monitoring reports, confirmation and follow-up letters according to Amarex SOPs and/or Sponsor requirements along with Amarex quality standards
- Oversee site study start-up procedures, including Institutional Review Board (IRB) submissions and contract/budget negotiations
- Serve as primary point of contact for site questions related to study conduct issues and study progress
- Assist in development of Case Report Forms (CRFs)/Electronic Data Capture (EDC) and the preparation of study manuals, informed consent documents, regulatory binders, source document templates, and other study materials
- Participate in project team meetings and communicate in a timely and effective manner, with the appropriate internal or external individuals involved in the project
- Establish regular lines of communication in addition to administering study-related training to assigned sites
- Recommend processes that lead to timely and successful placement, completion and/or resolution of project tasks
- Support the development of a subject recruitment plan

- Assure that regulatory and other required documents are complete and accurate, and are maintained and approved in accordance with required regulations, guidelines, and SOPs
- Evaluate the quality and integrity of site practices and escalate quality issues, as necessary
- Review source documents and CRF data to assure timely, accurate, and quality data retrieval
- Interface with study team to resolve data queries in a timely manner
- Contact and manage study vendors
- Oversee the ordering, tracking, and managing IP and trial materials
- Participate in the training and mentoring of Logistics Administrators (LAs), Clinical Trial Associates (CTAs), Clinical Data Associates (CDAs), as requested
- Other duties as assigned

REQUIRED EDUCATION AND EXPERIENCE

- Minimum of Bachelor's degree.
- Prior experience in clinical research monitoring is preferred.
- Working knowledge of ICH-GCP guidelines and US FDA regulations
- Strong English verbal and written communication skills
- Ability to work effectively both independently and in a team environment
- Strong organizational and planning skills
- Excellent interpersonal and professional skills
- Excellent time management skills with the ability to prioritize responsibilities and multitask
- Self motivated and detail oriented
- Proficient in Microsoft Office and able to learn appropriate software