Job Description

Department: Clinical Operations
Job Title: Senior Manager, Clinical Quality Liaison
Reports to: Director, Clinical Quality Liaison

Primary Objective of Position

The Senior Manager, Clinical Quality Liaison is responsible for the successful oversight of and clinical response to internal eTMF audits, site audits, external vendor audits and document audits within the Clinical Operations Department. The Senior Manager will provide directed oversight to the clinical project teams and will work with them to prepare appropriate and timely responses to audit findings; will work to promote data quality through eTMF support, and will work in collaboration with the Director, Clinical Quality Liaison to drive new procedures and processes within the department as appropriate.

Major Duties/Responsibilities

- Supports clinical project teams in preparing appropriate and timely responses to audit findings for site, eTMF, vendor, document and internal audits
- Provides oversight and guidance to Puma clinical project teams to ensure timely completion of periodic eTMF reviews and implementation of appropriate corrective actions; ensures outstanding issues are appropriately followed to resolution
- Partners with management and others to support functional and organizational initiatives, to drive new procedures and ideas, and to function as an advocate for processes and decisions
- Supports Clinical Operations quality standards by representing the department during audits, when requested
- Supports the electronic Trial Master File (eTMF) application (ie, Veeva Vault) as a Superuser and trainer, as required
- Supports the PROWL application (ie, document management) as a Superuser, as required
- Supports data quality as a Superuser of applicable electronic data capture systems, as required
- Provides support to the Document Specialist to ensure accurate and timely eTMF filing and maintenance according to ICH GCP guidelines
- Coaches and provides guidance to other Clinical Quality Liaison team members; may have supervisory responsibilities
- Engages in frequent cross-functional interactions with internal personnel (e.g., Quality Assurance, Data Management, Biostatistics)
- Assists with preparing and/or reviewing study-related and other internal documents
- Assists in the preparation and/or presentation of training documents/sessions/programs, as needed
- Assists the Director, Clinical Quality Liaison in any additional initiatives, as required

Skills & Abilities

- Strong verbal and written communication skills
- Strong organizational, problem-solving, conflict resolution, leadership and team-building skills
- Proficiency in developing and delivering educational materials, both written and oral
- Proficiency in required EDC applications

Physical Demands

The physical demands described are representative of those that must be met by an employee to successfully perform the primary functions of this position.

The physical demands of the office are normally association with extended amounts of time sitting and using office equipment, including a computer, keyboard and mouse, which can cause muscle strain. While performing the duties of this job, the employee is frequently required to stand, walk and sit. Periodic light lifting of supplies and materials may apply. Work is performed in an office environment.

Travel, as needed (up to 30%)

Education & Professional Experience

- Bachelor's degree or equivalent combination of education/experience in science or health-related field required
- Minimum 5 years of clinical research experience in pharmaceutical, biotech. or CRO company (preferably in Clinical Operations, Quality Assurance, Project Management and/or Clinical Data Management) required
- Strong understanding of FDA Regulations and ICH GCP Guidelines required
- Oncology experience
- Global trial experience
- Professional accreditation, membership in professional association(s), if applicable

Approvals

Employee

Signature_____ Title_____ Date_____

Supervisor

Signature_____ Title_____ Date_____