Position: Associate Director/Director, Clinical Quality Assurance

**JOB DESCRIPTION:**

The primary responsibility for this position will be managing/directing the ongoing Clinical QA activities to support GCP and Clinical Trial obligations. Position can be in either San Diego or Redwood City, CA.

**ESSENTIAL DUTIES & RESPONSIBILITIES:**

- Meet the ongoing needs of the quality assurance department by maintaining CQA compliance for ongoing and planned clinical trials
- Ensure proper maintenance of the clinical documentation databases and systems, e.g. Trial Master Files
- Directly interface with Clinical Operations to provide for vendor, site, and internal GCP audits.
- Work with Clinical Operations and Regulatory Affairs to review IND and NDA submission documents
- Responsible for ensuring submission data and documentation meets GCP guidelines
- Perform audits of clinical sites and CROs
- Perform periodic internal GCP trainings
- Create reports and track status of clinical documents
- Develop and support established records management procedures
- Provide input and change management for quality improvements affecting CQA systems
- Assist with writing and editing documents needed for the Clinical Quality Management System
- Update and maintain CQA SOPs that support the Quality Systems
- Support Clinical Development by reviewing and approving clinical documents in accordance with Clinical SOPs. Ensure maintenance of Clinical Release Investigator Databases.
- Purchase clinical support as needed for various studies, managing invoices and PO increases for clinical needs
- Manage and update electronic libraries
- Facilitate meetings with CRO’s and other clinical entities as appropriate
- Track action items and minutes for CQA meetings
- Ensure Trial Master Files and other GCP documents are tracked and maintained within standards

**REQUIREMENTS:**

- BS or BA degree or equivalent combination of education and experience in an FDA-regulated environment.
- Ten (10) years of related quality or clinical experience in a similar environment
- Broad knowledge of clinical processes and procedures, electronic documentation systems, and Good Clinical Practices 21CFR Parts 50, 56, and 312.
- Demonstrates initiative and proactively provides collaborative support to the clinical team.
- Ability to plan and organize work in an efficient manner, and work well under time constraints.
- Demonstrated effectiveness in maintaining CQA control systems for compliance with FDA regulations.
- Must have experience using Adobe Acrobat Professional, MS Word, Access, Excel, InfoPath, PowerPoint, SharePoint and Visio.
- Experience in Master Control is a plus.
- Willing to travel 20-30%

The above description is intended to describe the general nature of the job that may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.

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