**Clinical Trial Associate**

**Woburn, MA - 3 days onsite needed**

* **Must have 2 + years in clinical research experience.**
* **Must be fully vaccinated.**
* **Full time permanent role.**
* **Must be onsite in Woburn, MA at 3 days a week.**

We are a specialty pharmaceutical company developing transformative therapies to advance the treatment of gastrointestinal (GI) disorders. We focus on developing treatments for GI disorders for which meaningful therapeutic innovation is required to satisfy unmet patient need and disease burden.

The company offers a competitive compensation and benefits package as well as generous time off for a healthy work-life balance.

**Position Overview :**

Our client is looking for a Clinical Trial Assistant to join our Clinical Operations team! The Clinical Trial Assistant will work with the Clinical Operations team to provide administrative and project-specific support related to the conduct of clinical trials. This includes assisting with study team activities and perform administrative clerical duties. Also responsible for obtaining study materials and tracking of invoice and clinical study trackers. Adheres to Clinical Standard Operating Procedures and Good Clinical Practice ICH Guidelines.

**Specific Responsibilities:**

Responsible for the following activities:

• Assist in contacting investigator sites to provide study specific information

• Ensures receipt, completeness, and accuracy of clinical and administrative documents

• Coordinate distribution and shipment if study-related materials

• Coordinate investigator site/payments as needed

• Coordinate vendor payments as needed (tracking of invoice and payments)

• Maintains telephone contact with sites, contract research organization personnel, vendors and CRAs as needed

• Facilitates flow and maintenance of correspondence with sites

• Attends clinical project team meetings and takes minutes

• Contract, invoice and budget management and tracking

• Assists in coordination of study initiation documentation materials

**Responsible for compiling/QC checking/generating copies of clinical documents that are intended for submissions an include the following:**

• Investigators 1572s (original and updated)

• Informed Consent Form

• Protocol

• Investigator's Brochure

**Provides administrative support to Clinical Operations team members:**

• Performs administrative and clerical duties

• Coordinates distribution of study team materials and meeting minutes

• Drafts and prepares documents for mass mailings (eg protocol amendments)

• Assist with preparation of presentation materials

• Maintains central registry of contact information for clinical sites, contract research organizations, vendors, and CRA’s

• Sets up teleconference calls with sites and team and records minutes

• Create and maintains Central Clinical files

• Maintains central monitoring calendar for all site visits

Assist with system identification, implementation, and ongoing management of an electronic Trial Master File.

Perform other tasks as required

**Qualifications / Requirements:**

• 4-year degree is highly desirable in a scientific or health care discipline preferred.

• Minimum of 4 years of relevant work experience in Clinical Operations or related areas in a fast paced environment

• Excellent verbal and written communication skills

• Attention to detail

• Knowledge of medical terminology preferred

• Demonstrated ability to work independently

• Proficient in MS Office (Word, Excel, PowerPoint, Project)