



**Position Title:** Clinical Trial Assistant, I

**Reports to:** Associate Director or Director, Clinical Operations

**Department:** Clinical Operations

**Updated:** February 12<sup>th</sup>, 2018

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**General Summary:**

Responsible for assisting the clinical operations function and personnel assigned to the planning, execution and data collection activities on assigned clinical projects

**Principal Duties and Responsibilities:**

- Create study binders (pharmacy, regulatory etc.) and other study materials/supplies
- Ensure that all studies are conducted in compliance with GCP, relevant SOP's & regulatory requirements
- File documents in trial master file
- Assist study managers with clinical trial management as needed
- Communicate with sites and vendors upon request
- Assist in the review of protocols, informed consents and other study documents
- Collect regulatory documents
- Identify areas for process & technology improvement
- Manage the shipment of investigational drug and collect/file appropriate documentation
- Assist with the tracking of investigational drug supply
- Assist with laboratory sample shipments and reconciliation
- Assist with data management activities upon request

**Qualifications:**

**Education**

- Bachelor's degree in a life science (or in process bachelors degree) preferred or its equivalent in health care or biological science.

**Experience/Skills**

- Experienced self-motivated individual with a record of achievement as a result of past work experience
- Good conflict resolution and problem solving skills
- Strong interpersonal skills
- Ability to develop a culture of teamwork, collaboration and communication
- Excellent written and verbal skills and the ability to communicate clearly, concisely and effectively
- Open, available, transparent communicator

**Position Requirements:**

- Invest time to expedite and complete assignments or projects, as required
- High energy level, winning approach and the ability to advance group goals to meet company objectives

**NOTE: This description is not intended to be all inclusive or a limitation of the duties of the position. It is intended to describe the general nature of the job which may include other duties as assumed or assigned.**