VITAL THERAPIES®
TARGETING LIVER DISEASE

POSITION DESCRIPTION

Title: Clinical Documentation Specialist **Department:** Clinical

Position Overview:

Clinical Operations Associate supports our Clinical Operations with document management and reporting procedures.

Essential Duties and Responsibilities include, but are not limited to:

- Set up and maintenance of Trial Master File (TMF) as well as Investigator Site Files (ISF) under the oversight of the Director, Clinical Operations, in accordance with ICH GCP, FDA Regulations and VTL SOPs.
- Set up and maintain Regulatory files and support Regulatory submissions, in accordance with FDA, EMEA, ISO, ICH and GCP/GMP/GLP regulations/guidance's.
- Preparing site investigator files and materials in support of initiation of trial sites, plus oversee associated document management throughout maintenance and close-out portions of clinical trials.
- Perform interim, pre-closeout, pre-audit and pre inspection review of Trial Master File and Investigator Site File documentation in accordance with VTL SOPs, undertaken either at VTL or possibly at study site(s) if needs arise.
- Resupplying study sites with study administrative materials e.g. Regulatory binders, Case Report Forms (CRF's), etc. as well as augmenting efforts when necessary to administratively facilitate transfer of other site supplies.
- Liaising with sites regarding essential documents e.g. regulatory documents, CRF pages, data queries.
- Providing trial monitor/manager support as needed.
- Archiving, back up and encryption of trial related files, as applicable.
- Provision of template tracking logs and other study documents for study sites for use in ongoing studies/trials.
- Training/mentoring of staff at study sites in GCP documentation, archiving and filing when needed.
- Assist in the preparation of clinical study reports, protocols, publications, reports and presentations.
- Providing support for the coordination and planning of Investigator meetings and writing/distribution of minutes for these and other department meetings.
- Act as a liaison between the VTL Clinical Department personnel and investigator sites, when appropriate.
- Review monitoring reports and work with study sites to resolve administrative issues identified.

Position Requirements:

Education and Experience:

- High School diploma, BA/BS preferred
- 3-5 years of relevant experience in the clinical trials setting
- Understanding of FDA regulations, GCP and/ SOPs in clinical operations and/or regulatory context
- There is minimal travel associated with this position

Physical Requirements**:**

Physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Regularly required to sit and talk and hear. Employee frequently is required to use hands to finger, handle, or feel. Employee is occasionally required to stand, walk, and reach with hands and arms.

Occasionally required to stoop, kneel, and lift up to 50 pounds. Frequently required to work on a computer up to 8 hours a day.