Vital Therapies is hiring! www.vitaltherapies.com. We are an exciting life science company located in the Carmel Mountain Ranch area of San Diego. Vital Therapies is a pioneer in the treatment of acute liver failure. We are expanding our team and are currently hiring a **Clinical Operations Associate** to provide administrative support related to VTL Clinical Operations Department activity.

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

- Set up of Trial Master Files and Investigator Site Files under the oversight of the Sr. Director, Clinical Operations, in accordance with ICH GCP, FDA Regulations and VTL SOPs.
- 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 periodic review of Trial Master File and Investigator Site File documentation in accordance with VTL SOPs.
- Resupplying study sites with study administrative materials e.g. Regulatory binders, 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.
- 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 VTL staff on Clinical software systems e.g. eTMF, CTMS.
- Assist in the preparation of clinical study reports, protocols, publications, reports and presentations as requested.
- 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.
- Versioning and tracking of all controlled documents within the Clinical Operation department.
- Responsible for assisting Study Directors with tracking of study start-up documentation.
- Sending potential sites appropriate documents to assess interest in study participation.

VITAL THERAPIES
TARGETING LIVER DISEASE

Position Requirements:

Education and Experience:

- High School diploma, though BA/BS preferred
- 3-5 years of relevant experience in the clinical trials setting
- Understanding of FDA regulations, GCP and/ SOPs in the clinical operations and/or regulatory context

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. While performing the duties of this job, the employee is regularly required to use hands; reach with hands and arms; stoop, kneel, crouch, and talk or hear. Employee is frequently required to walk, sit and stand. Employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, distance vision, peripheral vision, depth perception, and ability to adjust focus.

Qualified candidates may submit **resumes and salary history** to **careers@vitaltherapies.com**
If you are submitting a resume from outside of San Diego, kindly include in your cover letter your relocation plans and timing to be able to report to work in our San Diego facility.

We are an Equal Opportunity Employer.