VITAL THERAPIES®
TARGETING LIVER DISEASE

Job Description

Vital Therapies is hiring! We are an exciting life science company located in the Carmel Mountain Ranch area of San Diego. Vital Therapies is a pioneer and recognized world leader in the treatment of acute liver failure. We are expanding our team and are currently hiring an **Associate Manager or Manager, QC Microbiology** with experience performing Quality Control testing and Environmental Monitoring within a current Good Manufacturing Practice (cGMP) environment.

Job Title: Associate Manager/Manager, QC Microbiology **Department:** Quality Control

Summary:
Responsible for oversight of Quality Control Microbiological testing, data review, reporting, and document management in accordance with current Good Manufacturing Practice (cGMP). Assists with packaging, labeling, releasing and shipment of ELAD C3A cell cartridges to Clinical sites.

Essential Duties and Responsibilities include, but are not limited to:
- Oversee Microbiological testing and review of Environmental Monitoring Data, and QC test data, Sterilization Records, and QC laboratory equipment usage, calibration, and maintenance.
- Ensure cGMP compliance in QC lab.
- Perform and /or Assist in QC-related internal and external audits.
- Identify and report non-conformances/deviations/out-of-specification events.
- Interact with Production, Quality Assurance, Regulatory Affairs and other Departments to provide testing data and other required quality-related information needed to support clinical studies.
- Write analytical method procedures and validation protocols/reports.
- Ensure the proper tracking and storage of test samples and associated controlled documentation.
- Maintain documentation, certifications, and training records for QC staff.
- Responsible for processing, incorporating, releasing, tracking, and training of QC-related new test procedures and SOPs and changes to the Test procedures/SOPs.
- Responsible for investigating and processing Deviations, Out of Specifications, and Out of Trend, QC events.
- Assist in packaging, labeling, releasing and shipping ELAD C3A cell cartridges to Clinical sites.
- Assist in reviewing of executed Manufacturing Batch Production Records.
- Ensure that clinical products are tested in compliance with cGMP regulations and in such a way as to ensure the identity, strength, quality and purity of the drug product.
- On call 24 hours a day, 7 days a week for sending ELAD to Clinical sites.

Position Requirements:
Education and Experience:
BS/BA or MS degree in Microbiology or related science or equivalent combination of education and experience.
Minimum of 5 years of Quality Control and Document Control in a cGMP environment is required.
Good computer skills with knowledge of Microsoft Word, and Excel are a must.
Method validation experience required.
Database validation and electronic document management system experience desired.

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. Frequently required to use hands to finger, handle, or feel. Occasionally required to stand, walk, and reach with hands and arms. Frequently required to work on a computer up to 8+ hours a day.

We offer a fast-paced work environment, competitive compensation, and a comprehensive benefits package. We are an Equal Opportunity Employer.

Qualified candidates may submit **resumes and salary history** to careers@vitaltherapies.com