VITAL THERAPIES®
TARGETING LIVER DISEASE

Director, Quality Control

We are currently seeking a **Director of Quality Control** responsible for oversight of Quality Control (QC Bioassay and QC Microbiology) 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:

- Direct the development and implementation of QC test methods and systems
- Oversee testing of raw materials, drug substance and drug product
- Review of QC test data, Sterilization Records, and QC laboratory equipment usage, calibration, and maintenance.
- Identify and investigate non-conformances/deviations/out-of-specification/Out of Trend events.
- Communicate cross-functionally with Production, Quality Assurance, Regulatory Affairs and other Departments to provide testing data and other required quality-related information needed to support clinical studies.
- Develop analytical method validation protocols/reports.
- Generate stability protocols and reports for starting materials and drug product.
- Ensure the proper tracking and storage of test samples, reference standards and associated controlled documentation.
- Maintain documentation, certifications, and training records for QC staff.
- Responsible for ensuring training of QC staff on new test procedures and SOPs and changes to the Test procedures/SOPs.
- Assist in packaging, labeling, releasing and shipping ELAD C3A cell cartridges to Clinical sites.
- Assist in reviewing of executed Manufacturing Batch Production Records.
- Perform and /or Assist in internal and external audits.
- Ensure cGMP compliance in QC lab and in such a way as to ensure the identity, strength, quality and purity of the drug product.

Position Requirements:

Education and Experience:

- BS/BA or MS degree in Chemistry or related science or equivalent combination of education and experience
- Minimum of 10 -15 years of Quality Control experience in a cGMP environment is required

Position Requirements (Cont.):

- Good computer skills with knowledge of Microsoft Word, and Excel are a must
- Method validation experience required
- 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. 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.

We offer a fast-paced work environment, competitive compensation, and a comprehensive benefits package.
Qualified candidates may submit **resumes** to careers@vitaltherapies.com

We are an Equal Opportunity Employer.