VITAL THERAPIES®
TARGETING LIVER DISEASE

Associate / Senior Associate, Quality Assurance

We are currently seeking an **Associate / Senior Associate of Quality Assurance** to support the different activities within the Quality Assurance Department. Primary responsibilities include performing line clearance, reviewing batch records and supporting documentation, generating or reviewing VTL GMP procedures and specifications, receiving inspection activities. The person will perform inspection readiness activities to ensure compliance with cGMPs and applicable SOPs and guidelines. This person will strive to reduce non-conformances in supported areas by proactively driving compliance as well as provide support during internal audits and regulatory inspections.

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

- Receiving inspection activities.
- QA line clearance activities.
- Review production batch records for accuracy, good documentation practice and completeness.
- Interact with manufacturing and facilities to resolve issues and ensure that applicable GMP records are generated e.g. Deviation, OOS, NCMR, CAPA, Change Control.
- Review GMP related processes and supporting documentation for compliance.
- Generate or review VTL procedures for accurate process description and compliance to regulations.
- Collaborate with different members of the QA/RA Department working on special projects.
- Support vendor audits.
- Support internal audits.
- Maintains a clean and safe work environment and follows all safety policies and procedures.

Position Requirements:

Education and Experience:

- Bachelor's degree is required, science-based major is preferred
- Minimum 2 years' experience in Quality within the life science industry, specific experience in cell and molecular biology laboratory is a plus
- Knowledge of cGMP or cGLP, FDA Quality System Regulations, ISO and Risk Management
- Familiarity with QC rules and their application within the laboratory and experience with regulatory or licensure aspects of the life science industry

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

Position Requirements (Cont.):

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.