VITAL THERAPIES®
TARGETING LIVER DISEASE

Validation Manager

We are currently seeking a **Validation Manager.** The Validation Manager is responsible for all aspects of the development, execution and maintenance of Validation activities at the cell cartridge manufacturing facility. The Validation Manager oversees and generates validation documents including plans, protocols and reports while ensuring compliance with cGMP requirements and current industry standards. The individual will be responsible for defining, implementing, and maintaining a robust biotech process validation program. Ensures the validation program is in compliance with regulatory agency expectations, and ensures the timely completion of validation deliverables for projects in order to meet scheduled timelines.

This position manages validation activities and schedules via close interactions with multifunctional groups while providing guidance for validation items. Manages the validation life cycle to ensure the ongoing validated status of systems and readiness for pre-approval inspection, internal audits and regulatory inspections. This position is responsible to defend validated systems during audits and regulatory inspections. A strong background in leadership is critical to this role with the demonstrated ability to support risk-based prioritization.

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

- Manage and oversee all validation activities at the cell cartridges MFG facility as part of BLA submission and preparation for commercialization.
- Responsible for the maintenance and oversight of the Validation Master Plan (VMP) and all related documentation.
- Generate, revise and approve validation documents ensuring compliance with QA, cGMP requirements and industry standards.
- Oversee the execution of validation protocols for equipment, utility systems, processes and control systems through commissioning, IQ, OQ and PQ phases.
- Review and approve reports for completed commissioning, IQ, OQ and PQ documents.
- Responsible for the generation, maintenance, and oversight of Validation Risk Assessments for the cell cartridge MFG facility.
- Responsible for pre-approval inspection readiness for all validated equipment and systems at the MFG facility.
- Responsible to present and defend validated systems during internal audits and regulatory inspections.
- Coordinates validation schedules with MFG, Facilities & Eng., QC/QA, and IT to facilitate smooth and efficient validation within the scope of the overall projects.
- Responsible for site training on the validation program.

Essential Duties and Responsibilities include, but are not limited to (Cont.):

- Assists in equipment selection, specification, and the application of a risk-based approach when determining qualification strategies.
- Managerial responsibilities include being fully responsible for work completion and development of subordinates. Duties include hiring, training, scheduling, directing, coaching, developing staff enthusiasm and engagement, making administrative decisions, and the completion of performance appraisals. Manage and direct contract resources in efforts to complete validation tasks.

Position Requirements:

Education and Experience:

- Bachelors in engineering with 7-10 years of validation experience in clinical and commercial pharmaceutical/biotech manufacturing.
- Prior staff and project management experience preferred.
- Direct experience in commissioning and qualification of critical utility systems, critical process equipment and computer systems.
- Knowledge of computerized software validation and 21 CFR Part 11 compliance.
- Experience in process and method validation.
- Experience with Regulatory filing (BLA, MMA) and representing Validation during FDA inspections.
- Expertise in FDA, EMA, and ICH qualification / validation requirements and creative risk based approaches for meeting and exceeding the minimum requirements.
- Experience in new facility start-up; facility design, commissioning and qualification is a plus.
- Knowledge in the fields of science and engineering with the ability to apply these concepts to define problems, collect data, establish facts, deal with concrete and abstract variables, and draw valid conclusions.
- Demonstrated situational leadership skills and project management expertise; ability to plan complex projects and accurately assess and manage resource requirements.
- Ability to manage multiple tasks and priorities, and establish short and long-term planning horizons to complete these duties.
- Knowledge of cGMP guidelines, international regulations as well as current good industry practice pertaining to sterile drug product produced by aseptic processing.
- Thorough understanding of key supporting quality systems including change control, deviation / non-conformance, and CAPA. Expertise in root cause analysis.
- Excellent analytical and problem solving skills coupled with strong presentation skills. Excellent communication skills, both verbal and written.
- Direct experience working in an aseptic formulation and fill manufacturing environment.

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

Physical 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.