VITAL THERAPIES®
TARGETING LIVER DISEASE

POSITION 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 a **Validation Engineer**.

Position Overview:

The Validation Engineer is responsible for activities related to commissioning/ qualification of GMP equipment/ systems and process validation at the cell cartridge manufacturing facility. Manage, schedule, coordinate, and execute assigned qualification or validation activities under the supervision of SME to ensure timely completion of validation projects in coordination with the User, Technical Operations, Quality Assurance and Regulatory departments. The Validation Engineer ensure that all process and laboratory equipment, facility and critical systems/utilities at the cell culture manufacturing facility are maintained in a validated state.

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

- Support all aspects of the validation life cycle from design through operation, improvement and retirement.
- Develop, review, approve and manage GxP system lifecycle documentation with support from Validation Experts, including Validation Plans, URS, FRS, testing protocols (IQ/OQ/PQ), Validation Reports, SOPs, Change Control Documentation, Risk Assessments, Validation Deviations and Qualification Summary Reports.
- Generate and execute commissioning, qualification and validation protocols such as FAT, SAT, IOQ, PQ, APV, PV.
- Analyze validation data and write final reports.
- Responsible for scheduling and executing equipment/ system requalification and periodic reviews and write final reports.
- Generate, maintain, and perform technical review of SOPs for validation activities and site SOPs.
- Conduct equipment and system risk assessments and impact assessments.
- Generate validation deviation and support investigation, troubleshooting and corrective actions to close out discrepancies and deviations in a timely matter.
- Support Validation SME in internal and regulatory agency audits.
- Generate, and revise validation documents ensuring compliance with QA, cGMP requirements and industry standards.
- Coordinate validation activities with, and seeks team supports from, Validation, Process Development, Manufacturing, Facilities & Engineering, Quality, third parties, and other groups on validation projects to ensure validation projects are carried out on time and budget.
- Assists in equipment selection, specification, and the application of a risk-based approach when determining qualification strategies.

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Position Requirements:

Education and Experience:

- Bachelor Degree, preferably in Engineering or related field.
- 3+ years of experience with Validation and Qualification of Facilities in the Pharma/Biotech/Biologics industries.
- Direct experience in commissioning and qualification of critical utility systems, critical process equipment (SAT, IOQ, PQ).
- Excellent verbal and written communication skills.
- Ability to manage multiple tasks and priorities.
- Knowledge of cGMP guidelines, international regulations as well as current good industry practice pertaining to sterile drug product produced by aseptic processing.
- Knowledge of key supporting quality systems including change control, deviation / non-conformance, and CAPA. Expertise in root cause analysis.
- Excellent analytical and problem solving skills.
- Knowledge of computer software validation and 21 CFR Part 11 compliance, process validation, media fill (APV), and analytical method validation is a plus.
- Direct experience working in an aseptic formulation and fill manufacturing environment is a plus.

Physical Requirements:

The 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 frequently lift and or move objects up to 50 pounds. Ability to stand/walk during entire length of shift. Use of arms, hands and fingers to handle, feel or reach. Ability to climb, balance, stoop, kneel, crouch, or crawl. Visual abilities include close, distance, color, peripheral, depth and ability to focus.

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** to careers@vitaltherapies.com