Title: Validation Engineer II
Location: Worcester, MA
Reports to: Senior Validation Manager

Join our team! At Mustang Bio we are driven by people. The patients we serve and the team we are building are the driving forces behind our mission to deliver life-changing first-in-class cells and gene therapies to patients with genetic diseases and aggressive forms of cancer.

Overview:

Mustang Bio is seeking an experienced Validation Engineer to provide ownership and expertise of Validation activities at our expanding Manufacturing facility in Worcester, MA. As a cGMP compliance subject matter expert, the successful candidate is responsible for the development and the execution of qualifications, validations, re-qualifications and re-validations for process equipment, laboratory equipment, utilities and facilities.

Responsibilities:

- Perform Qualification and Validation of Manufacturing Equipment, QC equipment, and Supply Chain equipment including Assessments, Design & Configuration, Installation, Operational & Performance Qualifications (cleaning, temperature mapping, sterilization)

- Coordinate the scheduling of validation execution by collaborating with all departments (Manufacturing Operations, Quality Control, Analytical Development & Process Development) and analyze the test results against pre-determined acceptance criteria

- Perform assessment of vendor change notifications (updates, calibrations, etc) to identify the impact on the validated status of equipment and GMP production

- Act as a liaison and assist Quality Assurance and Quality Control Departments in preparation for regulatory and internal audits

- Acquire and maintain an in-depth knowledge of the business domain and processes, understand user requirements, maintain deliverable metrics relevant to authoring, reviewing, and approving validation documentation

- Conduct and manage risk-based assessments to determine 21 CFR Part 11 compliance with Data Protection impact on Computerized Systems throughout the lifecycle
    - Collaborate with IT Infrastructure and Application support teams to ensure the operational processes such as change management, backup policy, configuration management etc are in place.

- Provide support and validation guidance to the IT Development/ QA organization and Project teams to ensure harmonized and consistent use of CSV standards, templates and procedures for computer system validation of Enterprise Systems with focus on GMP / regulated systems and technologies

- Create and maintain documentation templates to expedite documentation processes

Qualifications and Experience:

- B.S. in Engineering and 3-5 years of experience or related equivalent work experience within Life Sciences or medical device industry
- Experience with Computerized Systems Validation, testing and relevant regulations (US FDA 21 CFR Part 11, EU Annex 11 and GAMP 5)
- Effective at leading project teams and interfacing with customers and operations personnel
- Must be familiar with good documentation practices (GDP) and cGMP environments
- Experience with qualifying Gene Therapy lab Instruments such as ddPCRs, Flow Cytometers (Macsquant) and Roteas.
- Prior experience working in Quality Control or R&D labs is preferred