Position: Senior CSV Engineer
Location: Worcester, MA
Reporting to: 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 cell and gene therapies to patients with genetic diseases and aggressive forms of cancer.

Mustang Bio's success has created the need for an experienced Senior Validation Engineer to provide expertise, guidance, and maintenance of the Validation activities at our new, expanding Manufacturing facility in Worcester. As the CSV SME in validation, and in compliance with FDA and other related regulations, the Senior Validation Engineer leads the development, implementation and continuous improvement of Mustang's validation practices, policy, and procedures.

Responsibilities:

- Act as the CSV SME in validation SME for FDA, cGMP and health authority inspections.
- Documents User Requirements, Design Specification, Configuration Specification, Requirements Traceability. Produces Validation Plans, IQ/OQ/PQ Protocols, Summary Reports, test scripts, and SOPs as required to meet 21 CFR Parts 11 requirements, GAMP, among others.
- Responsible for the development and execution of CSV deliverables, as per the System Development Life Cycle (SDLC), such as Risk Assessments, Validation Plans, Change Impact Assessments, Design Specifications, User Requirements, Functional Requirements, Configuration Specification, Requirement Trace Matrices, IQ/OQ/UAT/PQ Protocols and Summary Reports.
- Assist user groups in troubleshooting and analyzing systems for cGMP manufacturing and testing.
- Provide regulatory guidance on principles of CSV to the expanded team.

Required Qualifications:

- 5 to 8+ years of validation experience in a biotech/pharmaceutical environment, specializing in Computer System Validation
- Bachelor's Degree in Engineering, Life Science or Computer Science
- Excellent working knowledge of process automation and computer system validation concepts, GAMP methodologies, CFR Part 11 Electronic Records and Signatures requirements and latest industry expectations for data integrity

Desired Skills and Experience:

- Lead the preparation, maintenance, revision, and approval of the site Validation Master Plan
- Lead the resolution of deviations noted during protocol execution
- Manage and approve vendor's documentations as appropriate
- Ability to impact and influence people/areas in matters related to CSV and GxP compliance
- Ability to work in a fast-moving, dynamic, small company environment
- Ability to mentor junior CSV team members
- Experiences in other validation areas which may include Lab Equipment/System qualification and Facility Equipment and Utility is a plus