TITLE:

Senior Validation Engineer

JOB SUMMARY:

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, MA. As the CSV SME in validation, and in compliance with FDA and other related regulations, the Senior Validation Engineer leads the development, implementation and is the driver of continuous improvement for Mustang's validation practices, policy, and procedures.

Duties & Responsibilities:

- Act as the CSV SME in validation SME for FDA, cGMP and health authority inspections.
- Lead the preparation and maintain, revision and approval of the site Validation Master Plan.
- 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.
- Authors and reviews validation project documentation as appropriate, 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.
- Lead the resolution of deviations noted during protocol execution.
- Manage and approve vendor's documentations as appropriate.
- Evaluates and analyzes validation data for accuracy and sufficiency.
- Assist user groups in troubleshooting and analyzing systems for cGMP manufacturing and testing.
- Work closely with IT, Operation, Regulatory Affairs, Clinical, QC and Quality to develop, coordinate and execute Validation documents and strategies.
- Provide regulatory guidance on principles of CSV to the expanded team.

Required Qualifications:

- 8+ years of validation experience in a biotech/pharmaceutical environment, specializing in Computer System Validation with strong experiences in other validation areas which may include Lab Equipment/System qualification and Facility Equipment and Utility.
- Bachelor's Degree in Engineering or equivalent technical discipline preferred.
- 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.
- 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.

Reporting to:

Validation Manager

Salary Grade/Level/Family/Range:

Commensurate to level of experience

Position Type/Expected Hours of Work:

Full-Time; flexible schedule within core operating hours between 9am – 3pm

Travel:

<10%, Regular travel is not expected for this position.