Title: Validation Manager

Location: Worcester

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.

Overview:

Mustang Bio is seeking an experienced Validation Manager to provide leadership, expertise, and guidance of the Validation function at our expanding Manufacturing facility in Worcester, MA. As leader of the Validation function, and in compliance with FDA and other related regulations, the Validation Manager is accountable for establishing and promoting strategy, managing development of resources, ensuring regulatory compliance and championing an environment of continuous improvement for Mustang's validation practices, policies, and procedures.

Duties & Responsibilities:

- Act as Validation SME for FDA, cGMP and health authority inspections
- Lead the preparation, revision and approval of the site validation master plan (VMP)
- Maintain and implement VMP schedules, including facility, equipment, and process qualifications
- Provide expertise in the development, execution and review of applicable validation documentation including, URSs, FRS, DOEs, SATs/FATs, IQs, OQs, and PQs in relation to equipment, facilities, utilities, automated systems, computer system validation, and cleaning processes
- Develop and maintain a requalification schedule for facilities, equipment and processes based o risk assessment, current industry "best practices", and regulatory requirements
- Assess change control activities, deviations and investigations impacting Validation
- Manage site Validation budget
- Manage staff and/or contractors to meet aggressive validation timelines
- Hire, mentor, train staff and other resources as needed

Required Qualifications:

- Bachelor's Degree in Engineering or equivalent technical discipline preferred
- 6+ years in a Senior Validation/Engineering Role within a GMP environment
- 2+ years in leadership and/or project leader role
- Excellent working knowledge of cGMP requirements on validation methods and principals, including ISPE, GAMP and FDA guidelines
- 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
- Sterile/aseptic manufacturing experience preferred
- Demonstrated ability to collaborate with all levels of management, validation staff, internal departments, and outside contractors/vendors
- Proven ability to work independently to manage multiple complex projects effectively in a fast-moving, dynamic small company environment