Title: Associate Director Clinical Quality Assurance
Location: Worcester MA
Reports to (title): Vice President of Quality

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:

We seek a highly motivated clinical quality assurance professional to be the point person for the Clinical Quality Assurance functions of the organization reporting to the VP of Quality. This position will work closely with Clinical Operations to develop, enhance and continually improve the quality and compliance of clinical processes.

Responsibilities:

Provide leadership to develop and maintain GCP/ICH compliant processes for conduct and QA oversight of clinical trials

Actively lead or assist with activities in the areas of Internal Quality Audits

Serve in an advisory/consultative role in compliance related manners, assist clinical program teams in implementing corrective and preventative actions and enable program teams to be inspection ready and support a culture of sustainable compliance

Lead an audit planning process to ensure trials are conducted in accordance with protocols, procedures and GCP/ICH requirements. Occasionally personally conduct trial site audits and site qualification visits

Assist in review of IND applications and other regulatory submissions

Serve as an active member of the Mustang QA management team

Participate in the review of clinical protocols/clinical source data to ensure compliant execution of clinical studies

Participate in the review of clinical study reports

Manage/review issues and occurrences from clinical studies to ensure GCP compliance, including evaluation of corrective and preventative actions

Lead training to QA and Clinical staff as necessary for GCP

Ensure the appropriate corrective and preventative actions are completed in a timely manner. Identify potential systemic gaps and coordinate with the appropriate stakeholder to ensure timely remediation to senior management.

Perform program specific root cause analysis of compliance issues and provide the appropriate metrics for tracking, trending for the overall QA reporting requirements to functional and senior management

Assist with the development of an overarching strategy related to proactive and sustainable compliance for assigned programs

Qualifications:

Bachelors Degree or equivalent experience in science or healthcare

Minimum of 5 years of experience in the Pharmaceutical/Biotech Industry with an in-depth and teaching capable knowledge of GCP/ICH E6 (R2) requirements for the conduct of clinical trials

At least 3 years working in a clinical quality assurance role

Must have a working knowledge of FDA GCP regulations and, ICH E6 (R2)

Broad experience in product development, clinical operations, regulatory compliance and GCP auditing

Demonstrated strong analytical, problem solving skills

Strong written and verbal communication skills

Detail oriented with good organizational traits

Strong leadership abilities

Strong network of clinical QA professionals

Experience with FDA BIMO inspections of clinical trials

Skills and Abilities:

Procedure writing

Data and facility auditing

Coaching/mentoring

Leadership/management