



Title: Quality Assurance Systems Specialist

Location: Worcester, MA

Reports to: Supervisor, Quality Assurance Systems

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 Quality or Regulatory professional to support our Quality Assurance Systems team in maintaining traditional Quality Systems (e.g., Change Control, Deviations, CAPAs, Investigations, Audits, etc.) with a primary responsibility to triage and assess proposed process and facility changes for impact.

Responsibilities:

- Review and triage proposed change orders including cross referencing with established regulatory submissions and dossiers to determine if an update or amendment is required
- Support the development, implementation, and management of an electronic solution to manage quality system activities
- Coordinate with QA and other teams to ensure appropriate updates to filings, dossiers, or other documents
- Work collaboratively to provide necessary detail to assure open lines of communication between the originator of the change and the impacted teams
- Facilitate and chair the Change Advisory Board (CAB)
- Support the reporting of metrics for quality system deliverables
- Provide end user support for the use and access of the electronic solution
- Participate in project work and initiatives associated with Quality System issues in conformance with regulatory requirements

Qualifications and Experience:

- Bachelor's degree in Chemistry, Biological Sciences or related scientific discipline with 4 years of experience in a Quality Assurance, Quality Systems, Quality Control, or Regulatory in the pharmaceutical, biotech, or medical device industry dealing with quality
- Working knowledge of what change management process is and how it functions in a GMP environment
- Ability to read regulatory dossiers (e.g., INDs)
- Ability to read and understand change plans
- Ability to set expectations
- Ability to work independently based on set expectations
- Familiarity with laboratory equipment validation
- Ability to problem-solve independently
- Strong organization, interpersonal and diplomatic skills
- Effective interviewing and solicitation skills in individual and group settings
- Ability to identify opportunities for process improvements and communicate appropriately