Title: Quality Assurance Specialist (CMC)
Location: Worcester
Reports to: Quality Assurance Specialist, Senior - Lead

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:

The Quality Specialist will support Quality Assurance operations and will be responsible for the review and release of completed cell and gene therapies, manufactured at Mustang Bio's Worcester MA facility. Mustang Bio, Inc. is a biopharmaceutical company focused on the development of novel immunotherapies based on groundbreaking Chimeric Antigen Receptor (CAR) research.

Responsibilities:

- Support CMC Quality Assurance operations
- Review and release of completed cell & gene therapies including batch record review
- Provide QA support in the areas of Drug Product Release, Change Management, Documentation Management, Nonconformance, Material Control, and Continuous Improvement while supporting a culture of quality at the site
- Demonstrate communication and organizational skills while effectively partnering with cross-functional teams to achieve site goals
- Review / approve controlled documents including study and validation protocols, reports, and procedures in the Documentation Management System
- Provide guidance for investigations of discrepancies, environmental monitoring excursions, out of tolerance test results, or failures related to manufacturing and control systems
- Assist in the auditing of manufacturing activities and internal audits; may be assigned to lead Process Audit activities at the site, document findings, and make recommendations for Continuous Improvement
- Perform review and approval of Quality Control test records and Production batch records (e.g., product release testing, stability, environmental monitoring, etc.) to support release of studies, materials, and product
- May support backroom activities during investigations / audit by regulatory authorities
- Participate in Failure Mode Effect Analysis and other Rick Management activities

Qualifications and Experience:

- 5+ years in Quality Assurance, Quality Systems, or Quality Control in pharmaceutical, biotech, or medical device industry dealing with quality
- Working knowledge of FDA cGMP requirements
- Attention to detail, organizational skills, and ability to multi-task in a dynamic environment