Title: Senior Quality Assurance Specialist
Location: Worcester
Reports to: Director, Quality Assurance

Overview: The Senior Quality Assurance Specialist is the primary Quality Assurance team member for the transfer, process development, and review / release process of products based upon Hematopoietic stem cells (HSCs). Additionally, the Senior Quality Assurance Specialist is responsible for the review and release of completed cell and gene therapies, manufactured at Mustang Bio's Worcester MA facility. This position requires a high level of organization, creativity, and self-motivation to solve challenges; and offers exposure to a variety of products while contributing to the creation of a quality system.

Only candidates with experience in the manufacturing, review, transfer, and release of Hematopoietic stem cells (HSCs) products will be considered.

Specific Responsibilities:

This position will support Quality Assurance and Operations and will be responsible for supporting the process and activities supporting gene therapies transfer and manufacturing.

- Coordinate the review and release of raw material, components, reagents, and finished goods across internal and supplier manufacturing sites. Including, the review and approval of Quality System documentation such as, but not limited to; Master Batch Records (MBR), Rework Plans, Deviation / Nonconformance Reports, Quality Control results / reports, and appropriately disposition affected materials.
- Provide guidance for investigations of discrepancies or failures related to manufacturing and control systems.
- Ensure non-conforming product is identified and appropriately controlled, and conforming product is appropriately dispositioned for use. This includes the preparation, review, and writing of the documentation to support the resolution of the discrepancies or failures.
- Drive the identification of correct root cause, implementation of corrective and preventive actions, and follow-up effectiveness reviews.
- Assist in the auditing of manufacturing activities and Internal Audits.
- Support audit by regulatory authorities.
- Review / approve Document Change Requests.
- Participates in project work and initiatives associated with Quality System issues in conformance to regulatory requirements.
- Interface and provide Compliance guidance/support to Operations.

About You:

Education: Bachelor's degree in Chemistry, Biological Sciences or related field, or equivalent combination of education and work experience.

Qualifications and Experience:

- 4 to 5 years in a Quality Assurance, Quality Systems, or Quality Control Role in the pharmaceutical, biotech, or medical device industry dealing with quality.

- Direct experience in the manufacturing and release of Hematopoietic stem cells (HSCs) materials and products.
- Knowledge of GMP, GCP, or GLP regulations and quality systems.
- Excellent attention to detail, organizational skills, and ability to multi-task in a dynamic environment.
- Additional experience with autologous T-cells, NK cells, or other blood cell products would be helpful for consideration.

Talents and Abilities:

- Ability to set expectations
- Strong interpersonal and diplomatic skills
- Effective interviewing and solicitation skills in individual and group settings
- Ability to work independently based on set expectations
- Identify opportunities for process improvements and communicate appropriately
- Ability to problem-solve independently
- Strong and effective organizational skills
- Ability to motivate others who have other reporting structures

About Us

Recent medical breakthroughs in cell and gene therapy have signaled a coming revolution in patient care for previously untreatable disease. Our multi-disciplined team at Mustang Bio is translating these breakthroughs into next-generation therapies for hematologic cancers, glioblastoma and rare genetic diseases. We expect to advance 2-3 new therapeutic candidates into the clinic annually and have developed the manufacturing expertise required to develop and commercialize these therapies on a broad scale.

We offer the opportunity to collaborate with a world-class team of cell and gene therapy experts in developing next generation medicines in areas of high patient need.