Title: Director/Senior Director Process Development

Location: Worcester, MA

Overview:
Mustang Bio, Inc.(MBIO) a member of the Fortress Biotech family of companies, is a clinical-stage biopharmaceutical company developing novel immunotherapies based on the ground breaking Chimeric Antigen Receptor (CAR) research by City of Hope. Mustang was formed to help bring this pioneering CAR research to as many patients as possible. Mustang, through a research agreement with COH, will develop CARs across multiple cancers, including for AML and Brain Cancer. In addition, Mustang in collaboration with St Jude, Memphis, is developing a gene therapy for XSCID. Mustang has its own manufacturing and research site in Worcester, MA where it employs more than 40 dedicated scientists to advance the pipeline.

Mustang Bio is seeking an experienced Director/Senior Director of Process Development to lead a team of scientists through expertise, guidance and oversight of the Process Development function at our Worcester, MA facility.

KEY RESPONSIBILITIES

- Manage MBIOs process development efforts with an emphasis on translating academic/R&D processes into scalable, robust methods suitable for industry and subsequent technology transfer into a GMP manufacturing environment.
- Establish strategy, project plans, and timelines for all process development activities over a range of different cell therapies to support the pipeline. Manage a team of scientists and engineers to achieve these goals on time and on budget.
- Effectively mentor and develop junior staff by helping to create a culture of excellence.
- Supervise development of methods intended for use in process development and scale up prior to technology transfer to GMP manufacturing.
- Effectively manage in a matrixed environment by regularly interfacing with diverse teams and functions including MSAT, Quality, Regulatory, Legal, Analytical Development, and Program Management.
- Author, review, and approve documentation for regulatory filings as needed including attending pertinent regulatory meetings.
- Monitor key scientific advances in the competitive landscape to provide insight into process and manufacturing technologies that offer an edge on the competition.

PROFESSIONAL EXPERIENCE/QUALIFICATIONS

- Bachelor's degree with 10+ years, Master's degree and 7+ years, or M.D. or Ph.D. and 5+ years of relevant experience in a biotechnology, cell therapy or pharmaceutical industry.
- Demonstrated competence and deep knowledge of mammalian cell culture process development, preferred experience in HSC, gene therapy or other immune cell therapies.
- Proven track record of publications and/or direct industry experience in gene therapy development; lentiviral applications preferred, HSC or T cell applications preferred.
- Strong communication skills with demonstrated ability to give effective presentations.

- Experience with Design of Experiments (DOE) and statistical tools for process tracking and trending.
- Knowledge of cGMP and cGLP requirements and applicable Regulatory Guidance documents is required. Specific experience in technology transfer is preferred.
- Experience with cell processing equipment is a plus.
- Ability to navigate and be successful in a fast-paced, highly-matrixed work environment.
- Demonstrated ability to lead productively and independently.
- Track record of managing and leading successful teams of process development scientists and in advancing programs through clinical development.