Title: Director Process Development
Location: Worcester, MA
Reports to: VP Preclinical Sciences

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:
Mustang Bio is seeking an experienced 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.

Responsibilities:

- Manage MBIOs process development efforts toward scalable, robust methods suitable for industry and subsequent technology transfer into a GMP manufacturing environment
- Manage phase-appropriate process development activities for transition from clinical trials to Biologics License Application (BLA) to commercialization
- 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

Experience:

- Advanced degree with 10 years of experience (5 in management) in the 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