Position: Head of CMC Development
Reporting to: Chief Technology Officer
Location: Worcester, MA

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.

Responsibilities:

- Drive CMC team performance to ensure successful regulatory submissions, IND, BLA, BLA prep, BLA execution, and post-BLA activity
- Develop and monitor key performance indicators for functional lines
- Maintain effective collaboration with CMOs (drug products and viral vectors) and Quality to ensure seamless technology transfer and handover of projects and knowledge
- Ensure compliance with internal / external requirements in all aspects of clinical manufacturing and quality
- Develop production plans to support clinical and commercial development and adjust plans as appropriate to meet corporate objectives
- Responsible for CMC sections of all global regulatory submissions in all phases of development
- Represent CMC in negotiations and communications with regulatory authorities
- Assist with the development and manage timely delivery of Quality documents for Regulatory submissions
- Proactively work with PD/AD to align CMC projects with overall product development plans, implement administrative and organizational processes for future knowledge transfer
- Setup and maintain CMC risk-management procedures in collaboration with Program Leads and manage continual improvement strategies for CMC
- In collaboration with functional lines, develop budgets for operations
- Act as an integrator within the development team and across the organization to ensure alignment and connect best practices
- Work with internal and external stakeholders to manage project deliverables, e.g. CMO's, Supply Chain, and support the planning and execution of tech transfers, qualifications, validations, and travel to sites as needed
- Proactively analyze manufacturing issues and coordinate potential resolution with the team

Experience:

- Advanced degree in science or engineering
- Minimum 15 years' experience in a biopharmaceutical/pharmaceutical manufacturing environment with at least 8-10 years of senior management experience
- Strong track record of effective management of contract manufacturing organizations
- Experience in Cell and Gene Therapies required
- Outstanding knowledge of FDA regulations required to ensure CMC development complies with all cGMPs
- Proven track record of regulatory submissions at all stages of product development
- Strong team player who puts a premium on building bridges and developing strong cross-functional interpersonal relationships
- Proven ability to effectively build and lead high-performing matrixed teams
- Comfortable working in matrixed teams
- An ability to inspire trust and followership in others through compelling influence, charisma, passion in her/his beliefs, and drive