Title: Head of Operations
Reporting to: Chief Technology Officer

Summary:

The Head of Operations is responsible for managing Facilities Engineering, Environmental Health and Safety (EH&S), Information Technology (IT), Supply Chain, and Validation (equipment, facility cleaning, and computerized systems) at Mustang Bio's Manufacturing facility in Worcester, MA. They will play a key management role in the development and management of strategic plans for continuous improvement of the existing facility, identification of expansion opportunities, facility expansions, and support of due diligence evaluations of CMO organizations. This position is also responsible for assuring that facilities, equipment, and computerized systems are maintained in a validated state according to Mustang Bio procedures, as well as managing the Environmental Health and Safety, Information Technology , and Supply Chain functions to meet business and regulatory requirements.

Duties & Responsibilities:

Facilities and Engineering:

- Ongoing maintenance and quality improvement of the manufacturing facility in Worcester MA
- Management of the expansion of the facility as well as commissioning and validation of the facility including new locations when needed
- Support development of mechanical / utility equipment and construction specifications
- Provide leadership for the oversight of cleaning and waste management contractors

Validation:

- Provide leadership to assure the preparation, revision, and approval of the site validation master plan (VMP)
- Manage the development, execution and review of applicable validation documentation including User Requirement Specifications (URS), Functional Requirement Specifications (FRS), Design of Experiments (DOE), Site Acceptance Testing/Facility Acceptance Testing (SAT/FAT), Installation Qualifications (IQ), Operation Qualifications (OQ), and Performance Qualifications (PQ) in relation to instrument, equipment, facilities, utilities, automated systems, computer system validation, and cleaning processes
- Using a risk-based approach, assure the development and maintenance of a requalification schedule for facilities, equipment and processes based regulatory requirements

Supply Chain:

- Manage the Supply Chain function and assure resources are properly received, stored and available when needed
- Interact with material/equipment vendors and commercial partners

Environmental Health and Safety:

- Ensure full compliance with applicable Health and Safety statutes (e.g., OSHA, Massachusetts Hazardous Substances Disclosure by Employers) are achieved and maintained

Information Technology:

- Manage the IT organization and assure development and maintenance of an IT master plan

General:

- Work closely with QA, QC, Validation, Project Management, Manufacturing, etc. to ensure company objectives are met on budget and on schedule
- Assure development of adequate Standard Operating Procedures (SOPs) for Facilities, Validation, EH&S, Supply Chain, & IT
- Act as point person for facilities, IT, validation, and supply chain during regulatory inspections.
- Hire, mentor, train staff and other resources as needed.

Required Qualifications:

- Minimum 10 years' experience in facilities engineering management (managing facilities & infrastructure in clinical/commercial & sterile/aseptic manufacturing of biological or cell/gene therapy products preferred)
- Working understanding of requirements for validation of facilities, equipment, and computerized systems
- Experience providing strategic direction & leadership to diverse functions including supply chain, EH&S and IT
- A thorough applied understanding of cGMP requirements for clinical and commercial manufacturing
- Excellent communication skills, both oral and written
- Experience building & leading a high performing team
- Ability to evaluate technical data and write technical documents