Title: Head of Regulatory Affairs (Oncology/Rare Disease)
Location: Worcester, MA
Reports to: CEO

Overview

The Head of Regulatory Affairs will support activities required to progress our novel therapeutic programs through preclinical and clinical development and ensure alignment within the company and regulatory agencies. This is a unique opportunity to work in multiple therapeutic areas developing novel technologies in the cell and gene therapy space. As the Head of Regulatory Affairs, this individual will be responsible for representing Regulatory Affairs in cross disciplinary areas and manage high-quality submissions to regulatory agencies. As Mustang continues to develop novel assets, there could be additional duties and responsibilities to this role, including the expansion and management of additional team members. The Head of Regulatory Affairs will interact directly with members of the Mustang Leadership Team and will provide detailed regulatory guidance as needed. Additionally, the Head of Regulatory Affairs will represent Mustang Regulatory in external partnerships and collaborations.

Specific Responsibilities

- Represent Regulatory Affairs on project sub teams, especially Clinical and Nonclinical
- Provide regulatory strategy and guidance for teams (e.g., protocol reviews, report reviews, development plans)
- Responsible for preparing for regulatory agency meetings (e.g., Pre-IND, Type B & C, Pre BLA/MAA/NDS)
- Prepare regulatory submissions including INDs, CTAs, annual reports, BLAs, MAAs, briefing packages as well as orphan drug designation documents
- Write regulatory documents to support regulatory submissions
- Interact with regulatory agencies
- Develop and implement innovative and creative regulatory strategies for timely submission and approval of pre-clinical submissions, applications for clinical trials, marketing applications, etc.
- Provide expertise in translating regulatory requirements into practical, workable plans.
- Coordinate with external publishing resources for on-time delivery of high-quality regulatory submissions to regulatory agencies
- Establish and maintain Clinical Trials.gov postings for supported studies
- Participate in regulatory intelligence gathering activities and maintain knowledge of US and EU regulatory requirements
- Ensure compliance with regulatory requirements and timely preparation of organized and scientifically valid applications

About You

Education: Bachelor's degree in life sciences required; advanced degree preferred

Qualifications and Experience:

- Minimum of 10 years of Regulatory Affairs experience
- Experience working with breakthrough status, fast track, and rare/orphan rare designations is a plus
- Experience with the CBER (large molecules and cell/gene therapy) divisions of FDA is a plus
- Thorough knowledge and understanding of guidances governing biologics/ oncology in all phases of development in the US and EU
- Solid understanding and ability to interpret complex scientific issues across projects and therapeutic areas of responsibility as it relates to regulatory requirements and strategy
- Experience managing multiple filings and evidence of successful submissions to FDA (e.g., INDs, briefing packages)
- Demonstrated evidence of writing of regulatory documents (Module 1, Module 2, briefing packages)
- Knowledge of FDA and ICH regulations and guidelines a must
- Excellent written and oral communication skills, interpersonal skills, and project management skills and a drive for excellence

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.

We are an equal opportunity employer and value diversity. All employment is decided on the basis of qualifications, merit and business need. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.