Title: Manager, Regulatory Affairs
Location: Worcester, MA
Reports to: Head, Regulatory Affairs

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

We seek an experienced clinical/nonclinical regulatory affairs manager. This role is responsible for the overall planning and execution of clinical/nonclinical regulatory activities for Mustang's cell and gene therapy programs. He/she will provide strategic and tactical guidance to teams, including regulatory review of clinical trial documents, to achieve timely and efficient development and maintenance of programs, while ensuring compliance with applicable regulatory requirements.

Specific Responsibilities

- Formulate and lead clinical/nonclinical regulatory strategy for multiple projects/teams simultaneously with a focus on innovation and business objectives
- Ensure regulatory compliance and timely implementation of health authority advice and/or execution of commitments to regulatory authorities
- Lead and implement global clinical/nonclinical submission activities (planning, authoring, editing, reviewing, coordination, submission) for assigned projects/products in accordance with global regulatory strategies, current regulatory trends and guidelines, technical congruency, and regulatory compliance
- Maintain regulatory chronologies and correspondence with regulatory authorities
- Represent Regulatory in cross-functional team meetings to provide strategic direction and guidance
- Participate in agency meetings
- Identify and communicate potential issues/gaps in program specific clinical/nonclinical development strategies/dossiers and propose creative risk mitigation strategies
- Track and communicate implications of global regulatory clinical/nonclinical requirements for assigned projects to the broader organization (e.g. health authority guidance's/guidelines, regulatory policies, overall environment)
- Identify and draft necessary SOPs and/or Work Instructions for Regulatory Affairs, as requested
- Perform regulatory precedence and competitive intelligence research, as requested

Qualifications & Experience

- BS/BA in a scientific discipline; advanced degree (MS) and/or RAC certification desirable
- Minimum of 4 years of clinical/nonclinical regulatory development experience in the biotechnology/ biopharma/ pharma industry, with at least 2 years in biologics ideally in cell and/or gene therapy
- Prior IND experience required; ex-US and BLA experience highly desirable
- Strong working knowledge of eCTD
- Demonstrated working knowledge/experience in drafting, filing, and maintaining high quality global regulatory applications with FDA, EMA, and similar Global Health Agencies
- Strong working knowledge of regulatory requirements both domestically and internationally including ICH GCP regulations
- Experienced and knowledgeable in managing regulatory submission preparations and reviews, including Investigational New Drug applications (INDs)/Clinical Trial Applications (CTAs), clinical protocols, Investigator's Brochures (IBs), and annual reports

- Ability to understand, interpret and advise teams on regulations, guidelines, procedures, and policies on the development of cell/gene therapies to ideally expedite the submission, review, and approval of global regulatory applications
- Ability to understand and interpret scientific data as it relates to regulatory requirements and strategy for assigned projects
- Self-motivated, flexible, and creative thinker with an ability to prioritize, multi-task, and thrive in a fast-paced & demanding environment
- Ability to work independently and successfully with cross-functional project teams and external partners/collaborators
- Ability to analyze problems, identify alternative solutions, and implement recommendations for resolution
- Strong team player who demonstrates ownership and looks for opportunities for continuous improvement
- Excellent interpersonal skills, with a calm demeanor and positive attitude under pressure
- Excellent communication skills, both written and verbal