Title: Regulatory Affairs Manager, CMC
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 a skilled CMC Regulatory Affairs Manager. This role is responsible for the development and implementation of global CMC regulatory strategy for Mustang's cell and gene therapy programs, and will support CMC Teams and provide direction on the interpretation and application of global CMC regulations and guidance.

Specific Responsibilities

- Formulate and lead CMC regulatory strategy for multiple projects/teams simultaneously with a focus on innovation and business objectives
- Responsible for CMC focused aspects of INDs, CTAs, Amendments, Regulatory Designation Requests, Marketing Applications, briefing books; meeting preparations and Responses to Health Authority questions
- Lead and implement global CMC 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
- Represent CMC Regulatory in cross-functional team meetings to provide strategic direction and guidance
- Track and communicate implications of global regulatory CMC requirements (e.g., health authority guidance's/guidelines, regulatory policies, overall environment)
- Identify and communicate potential CMC issues/gaps in program specific CMC development strategies/dossiers and propose creative risk mitigation strategies
- Review documents in change control in order to ensure that they meet regulatory requirements
- Ensures regulatory compliance and timely implementation of health authority advice/commitment based on maintenance of RA interactions/ feedback
- Perform regulatory precedence and competitive intelligence research

About You

Education: BA/BS degree in Life/Health Sciences (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology). Advanced degree (MS) and RAC certification desirable.

Qualifications and Experience:

- Minimum of 4 years of biologics regulatory development experience in the biotechnology/ biopharma/ pharma industry, with at least 2 years ideally in cell and/or gene therapy
- Prior IND experience required; BLA experience desirable.

- Demonstrated working knowledge/experience in chemistry/biotechnology, analytics or pharmaceutical technology highly desired

Skills and Abilities:

- Knowledge and understanding of US and international regulations including ICH guidelines
- Experienced and knowledgeable in the preparation of global regulatory submissions including maintenance activities throughout all phases of development
- Demonstrated ability to handle complex global CMC issues through continuous change and improvement throughout the products lifecycle
- Ability to understand, interpret and advise teams on regulations, guidelines, procedures and policies relating to development, registration and manufacture of new pharmaceutical products, to expedite submission, review and approval of global CMC applications
- Self-motivated, flexible and creative leader, able to prioritize, multi-task, and work in a fast-paced & demanding environment.
- Strong team player who demonstrates ownership and looks for opportunities for continuous improvement
- Ability to work independently and successfully with cross-functional project teams and external partners/collaborators
- Well-developed planning, organizational, negotiation, analytical problem solving and interpersonal skills
- Strong critical and logical thinker with ability to analyze problems, identify alternative solutions, and implement recommendations for resolution
- Good oral and written communication skills with a collaborative and patient-focused approach