Job Description
Director, Regulatory Affairs (CMC)

At Sesen Bio, we are committed to renewing life for people with cancer. We are a late-stage clinical company advancing fusion protein therapies based on our Targeted Protein Therapeutics platform. Our lead program, Vicinium™, also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA Trial, for the treatment of high-grade non-muscle invasive bladder cancer. Twelve-month data from the trial are anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells while sparing healthy cells.

The Opportunity

The Director of Regulatory Affairs (CMC) provides regulatory leadership in support of the late-stage and early development programs at Sesen Bio. The successful candidate will provide the strategic guidance for CMC regulatory activities necessary to conduct clinical trials, achieve marketing approval of drug candidates and ultimately support the life-cycle of approved products. This includes developing and implementing the strategic plans in collaboration with the Quality Assurance, manufacturing, and Development Teams, ensuring timely preparation, review and submission of documents to regulatory authorities, and maintaining compliance with applicable regulatory requirements.

This person represents the regulatory function on multi-disciplinary CMC product development teams and with external entities. The person in this role serves as a resource to CMC team members for the regulatory requirements, processes, and logistics to conduct global drug development activities for compounds from the preclinical stage through to the initial marketing application, and life cycle management.

Responsibilities:

- Lead all CMC regulatory affairs activities for designated programs in line with US, European, ICH, and other applicable requirements.
- Coordinate with Quality Assurance, Development and other functional areas to implement CMC regulatory strategy.
- Act as the primary representative with external consultants for CMC matters.
- Plan, prepare, and review submissions to regulatory authorities including FDA, EMA and other national authorities to support clinical trials and marketing applications.
- Represent the regulatory function on development teams providing CMC regulatory guidance and strategy including identifying and assessing regulatory risks.
- Ensure that regulatory documents are accurate, complete and verifiable against source documents to confirm compliance with regulatory requirements and traceability.
- Evaluation of manufacturing processes and changes, assessment of regulatory implications and supporting their implementation.
- Maintain current knowledge of the relevant guidelines and regulations and determine applicability to Sesen Bio activities.
- Contribute to and participate in health authority meetings.

Requirements:

- A bachelor's degree in a life science, an advanced degree is preferred
- At least 8 years of CMC regulatory affairs experience
- Knowledge and understanding of global regulatory regulations and guidelines
- Previous experience in the preparation and submission of the CMC components of IND/CTA/BLA/MAAs
- Strong interpersonal skills and the ability to deal effectively with representatives across disciplines
- Ability to work in a cross-functional team environment and manage competing priorities
- Strong attention to detail and excellent organizational, computer, and documentation skills

This role is primarily based in Philadelphia, PA. For the right candidate, there are opportunities to work remotely and come into the office on a regular basis.

To apply, please send your resume to careers@sesenbio.com.

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