Senior Vice President, Global Regulatory Affairs, Quality Assurance and Drug Safety

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.

Position Overview:

The Senior Vice President, Global Regulatory Affairs, Quality Assurance, and Drug Safety will be accountable for the development, implementation and maintenance of the company's Regulatory, Quality Assurance, and Drug Safety policies to ensure compliance with internal policies, procedures, requirements, and external regulations and standards (FDA/EMEA). This position will manage all global regulatory activities for products, including all phases of product development to support US and international regulatory filings and product registration activities. The person selected for this position will participate on project teams and interact extensively with all departments to facilitate the planning and execution of regulatory agency submissions. This position will report to the CEO.

Responsibilities:

- Lead the Global Regulatory, Quality Assurance, and Safety functions
- Develop, establish and maintain the Regulatory, QA, and Drug Safety programs, policies, and procedures to ensure compliance
- Provide and/or guide strategic regulatory representation and oversight on project teams
- Collaborate with partners/consultants to ensure successful global registration planning and implementation
- Lead and develop regulatory, QA and safety/pharmacovigilace staff; ensure ongoing professional development of the team
- Identify and Integrate regulatory strategies in support of the company strategy
- Communicate regulatory policies and provide clarity on regulatory expectations when needed
- Develop and maintain a global safety database
- Review reports and documents for approval
- Conduct regulatory due diligence, as needed
- Develop and oversee promotional review

Requirements:

- Master’s degree in chemistry, life sciences or a related field required. Advanced degree preferred
- At least 15 years of biopharmaceutical / pharmaceutical experience with five years of experience in managing a Regulatory/QA/Safety function required
- Experience and knowledge in oncology

- Strong knowledge of cGMP regulations, practices, and trends pertaining to biopharmaceutical / pharmaceutical product development, manufacturing and testing also required
- Familiarity with compliance and filling requirements of the FDA and EMA as well as other international regulatory agencies preferred