DIRECTOR, PHARMACOVIGILANCE

Job Summary

Sesen Bio is seeking a strategic leader for the role of Director, Pharmacovigilance (PV) to support our VP, Medical Affairs. This role will lead project management and operational activities for multiple complex projects and programs working closely with Sesen Bio colleagues. This role is responsible for overseeing the PV requirements for Sesen Bio, including primary oversight of PV vendor(s). The person will oversee the operations related to PV for post-approval activities, ensuring compliance with all relevant regulations. The individual will be responsible for oversight and execution related to event case management, the drug safety database, and collaboration supporting risk management and PV for Sesen Bio's products.

The position title and level will be determined by candidate experience and accomplishments.

Responsibilities

- Provide strategic leadership and oversight for PV Operations and Compliance activities
- Ensures compliance with US and international pharmacovigilance regulations and Adverse Events (AE) reporting requirements related to Sesen Bio products.
- Lead PV for the US and support/manage data from Sesen Bio's OUS partners.
- Oversee the management of Adverse Event, Serious Adverse Event (SAE), and Suspected Unexpected Serious Adverse Event reporting (SUSAR) activities for approved products.
- Lead PV vendor selection and vendor management
- Develop and maintain Standard Operating Procedures (SOP), Forms, Templates, and Guidelines to ensure compliance.
- Organize and execute safety governance meetings (consistent with SOPs) for Safety Management Team (SMT) and Safety Board.
- Works closely with the heads of Clinical Development and Regulatory, serving as a lead representative in organizing and communicating with Regulatory authorities on pharmacovigilance and labeling matters, as required.
- Collaborate with Regulatory colleagues to ensure successful inspection activities.
- Support signal management activities, safety, and benefit-risk evaluations and oversee vendor preparation of aggerate reports (eg, Periodic Adverse Drug Event (PADER), Drug Safety Update Reports (DSUR), etc.)

- Significantly contributes to development of Safety sections of NDA/MAAs and other regulatory submissions (e.g., integrated summary of safety, and/or summary of clinical safety, Pharmacovigilance System Master File (PSMF), Risk Management Plans (RMP), etc.).
- Coordinates with Corporate Compliance to ensure the provision of relevant pharmacovigilance training throughout Sesen Bio.
- Compiles and delivers performance metrics to Senior Management on a regular basis and provides data to address additional ad hoc requests.
- Assumes responsibility for other activities as they emerge based on business needs.

Qualifications

- MD, PharmD, NP or PhD in related scientific field and 6+ years of combined experience in biotech/pharmaceutical drug safety and pharmacovigilance compliance.
- BS/BA or RN degree in related scientific field and 8+ years of experience as described above.
- Experience in supporting regulatory authority inspections required.
- Managerial / functional management or lead experience preferred.
- Experience with drug safety databases such as Argus.
- Proficiency with safety coding dictionaries (eg, MedDRA, WHODRUG).
- Strong knowledge of US and International pharmacovigilance regulatory requirements
- In-depth knowledge of drug development process, safety monitoring, and risk/benefit analysis in clinical trials.
- Experience with the writing/reviewing of safety documents such as DSURs, Investigator's Brochure (IB), Periodic Benefit-Risk Evaluation Report (PBRERs)/PADERs, responses to Health Authority requests, submission documents and safety labels.
- Ability to evaluate, interpret and synthesize scientific data.
- Expertise in individual safety case report processing, including triage, data entry, quality review, and submission.
- Team player with ability to work cross-functionally in a highly virtual environment.
- Strong vendor management, leadership and communication skills.
- Integrity with high ethical standards that reflect the vision of Sesen Bio.
- Well organized self-starter, able to handle multiple priorities and work across all levels of an organization.

- Ability to excel at working in a high energy, professional environment at a company preparing for approval and commercialization of its product.
- A creative problem solver, with an entrepreneurial mindset.
- Integrity with high ethical standards that reflect the vision of Sesen Bio.
- A creative problem solver, with an entrepreneurial mindset
- Less than 20% travel.

About Sesen Bio

We are passionate in our commitment to save and improve the lives of patients. Sesen Bio is a late-stage company developing fusion protein medicines for the treatment of patients with cancer. In February 2021, the FDA accepted for filing the Company's BLA for Vicineum™, a potential best-in-class treatment for non-muscle invasive bladder cancer.

Sesen Bio is proud to be an Equal Opportunity Employer. Our goal is to have a diverse workforce. We do not discriminate on the basis of race, age, color, religion, national origin, gender, sexual orientation, gender identity or expression, veteran status or disability or any other status protected under federal, state or local law. All employment is decided on the basis of qualifications, merit and business need.

For the safety of our employees and communities in response to COVID-19, Sesen Bio has implemented a temporary work from home policy. All interviews are conducted virtually at this time.