Open Position
Drug Safety Reviewer
Location
San Diego, CA

About
Biosplice Therapeutics, Inc. is a pharmaceutical platform company based in San Diego, California, focused on developing first-in-class, small-molecule therapeutics based on pioneering science of alternative pre-mRNA splicing. Stemming from foundational discoveries in Wnt pathway modulation, Biosplice has elucidated novel biology linking CLK/DYRK kinases to the therapeutic regulation of alternative splicing. Alternative splicing is an essential biological mechanism that regulates the diversification of proteins in a cell, which, in turn, determines cell type and function. Biosplice’s target class governs the selection of tissue-specific mRNA splice sites, making them attractive, druggable targets within the cellular “command and control” center. Biosplice’s drugs in clinical development include lorecivivint for osteoarthritis (in Phase 3), cirtuvivint for numerous cancers, and a broad pipeline that ranges from Alzheimer’s disease to other degenerative conditions. Learn more at https://www.biosplice.com

Job Description:
We are seeking a responsible, dynamic, creative and highly motivated Drug Safety Reviewer to join our DSPV team. This is a full-time position in the company’s San Diego headquarters. This position provides medical expertise to the safety and pharmacovigilance department for the clinical development program. S/he will contribute to the review, analysis, and approval of Individual Case Safety Reports (ICSR) and Periodic Reports for investigational products. S/he will maintain active pharmacovigilance oversight for products, including signal detection, and will provide safety/medical input for review of risk management. Will act as the lead for the safety monthly reviews in collaboration with the clinical development physicians.

Responsibilities:
- Provides pharmacovigilance and safety management expertise across multiple programs at Samumed.
- Performs medical review for ICSRs and Analyses of Similar Events (AOSE) in the global safety database.
- Performs weekly review of safety data to ensure no serious adverse event has been inadvertently missed.
- Contributes to the safety section of protocol synopses, study protocols, INDs, DSURs, and CSRs.
- Conducts structured reviews of safety profiles for all products in development on a monthly basis or as required.
- Prepares, leads, and facilitates safety monthly reviews in collaboration with DSPV and Clinical developments representatives, and prepares/presents safety data at these meetings. Collaborates with other functions as necessary for safety assessments and ad-hoc signal detection activities as required.
- Provides medical input to decisions related to recall of clinical supplies.
• Contributes to analysis, preparation, and development of Risk Management Plans (RMPs) as needed.
• Develops molecule-specific RMP strategy, including elements that require strategic cross-functional input and alignment.
• Reviews any safety concerns escalated from internal and external stakeholders, including regulatory authorities.
• Reviews potential issues that could be expected to lead to an urgent safety measure or restriction in development drugs (including, but not limited to, premature termination or suspension of a trial), and provides recommendations for review and approval by the Safety Advisory Committee.
• Assists the head of DSPV in the preparation, facilitation, and documentation of safety governance meetings.
• Presents safety data at the safety governance meetings.
• Provides Safety Reporting training at investigators’ meetings.
• Ensures that DSPV timelines for medical review are followed.
• Collaborates with medical reviewers in clinical development, on a case by case basis, to ensure alignment of medical review.
• Reviews and communicates safety data trending, signaling, and other safety-related issues originating from any source for the purposes of detecting and reviewing safety signals (e.g., change in frequency, nature, or severity of a safety-related issue) in a timely manner via the Safety Governance process.
• Participates in the development and implementation of risk mitigation actions.
• Works with other DSPV team members in the preparation of DSPV dashboard and key performance indicators (metrics) for key safety surveillance activities that are pertinent to medical review / safety data review.
• Oversees the safety activities regarding events of clinical interest, AESI’s, as applicable by program.
• In addition, working with the Clinical Development, Regulatory, and Clinical Operations function:
  o Co-ordinate activities of the drug-development continuum, for all assets until the protocol is final for a given clinical trial.
  o Develop clinical concepts, protocol synopses, and final trial protocols.
  o Provide coordination and endorsement of clinical concept, development of protocol synopses and final protocols.
  o Assess operational feasibility of proposed clinical trials in the process of protocol development.

Requirements:
• Doctoral-level degree in medicine.
• 3+ years’ experience in drug safety and pharmacovigilance.
• Strong understanding of the use of medical terminology and of drug-names in multiple nations and environments.
• Proficiency in Argus.
• Proficient with Microsoft Office Suite (Word, Excel), databases, email, internet, and smart phones
• Excellent verbal and written communication skills (proficient in English) as well as strong presentation skills.
• Ability to multitask under tight deadlines while providing attention to detail and high-quality work in a dynamic environment.
• Ability to be flexible, adapt to change, work independently, as well as experience working in a matrix environment.
• Demonstrate commitment and support for company goals, objectives and procedures.
• Demonstrate professionalism and adherence to moral, ethical and quality principles.
• Comply with applicable regulations, GCP and corporate policies and procedures.

TO APPLY, PLEASE EMAIL RESUME TO APPLY@BIOSPlice.COM

NO phone calls please.