Open Position
Safety Associate/Manager

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 and Responsibilities:
We are seeking a responsible, dynamic, creative and highly motivated Safety Associate/Manager to join our Drug Safety and Pharmacovigilance team. The Safety Associate/Manager provides scientific/clinical expertise to Individual Case Safety Reports (ICSR) management and SAE reconciliation as lead, including providing vendor management of relevant activities and PV compliance. Provides oversight of the Argus global safety database as subject matter expert (SME), workflow manager, and system administrator. This is a full-time position in the company’s San Diego headquarters.

Specific responsibilities of the position include:
• Act as system administrator for Biosplice’s global safety database (Argus), including providing vendor oversight to the Argus cloud hosting provider.
• Provide operational leadership for ICSR workflow, overseeing the case management activities in Argus and ensuring critical timelines and compliance are met.
• Monitor and ensures compliance with worldwide regulations, case management and regulatory reporting timelines, workflow deliverables, and KPIs.
• Monitor activities of CROs/business partners to ensure adherence and compliance with applicable Safety Monitoring Plans, other study plans, metrics, and contractual agreements.
• Perform triage for incoming cases (assessing seriousness, listedness, and causality)
• Serve as SME/lead for PV compliance and inspection and audit readiness for all Argus, workflow, KPIs, and case management- related topics.
• Author high quality case narratives and collaborate on the development of analyses of similar events for the medical review of ICSR’s including identifying relevant information from source documents.
• Ensure appropriate MedDRA and WHO Drug coding
• Produce accurate safety reports (i.e., CIOMS/MedWatch Forms) for submission to regulatory authorities and partners.
• Track due dates for regulatory submissions.
• Provide oversight to reconciliation of the safety and clinical databases for serious adverse events, collaborating with data management and other stakeholders and follow up with sites to resolve discrepancies, as needed.
• Conduct peer review of cases in the safety database for quality control (quality review step in the global safety database)
• Generate safety queries as needed for clarification of clinical reports.
• Conduct active case follow-up, including written and verbal follow-up with clinical investigators and sites.
• Author SMPs and facilitate activities during project/study start-up phase, including cross-functional interactions.
• Collaborates with Medical Directors, Clinical Operations, Regulatory Affairs, Data Management, Biostatistics, and PV Vendor’s clinical staff in providing pharmacovigilance support for ongoing clinical trials to ensure integration of safety data collection, review, processing, and reporting.
• Review, update and maintain Data Entry Conventions, as applicable
• Support other pharmacovigilance activities, as needed.

Requirements:
• Bachelor of Science Degree or higher in a healthcare discipline (e.g. pharmacy, nursing)
• 5+ years’ experience in drug safety/pharmacovigilance in a case processing role in the biotech/pharmaceutical industry in a CRO or pharmaceutical setting
• Strong working knowledge of Argus Safety Database in an administration capacity
• Vendor management experience preferred
• Expertise in ICSR processing, including triage, data entry, quality review and submission.
• Strong understanding of local and global safety regulations, medical terminology, and drug development process
• Strong clinical background, with ability to interpret medical records (e.g. laboratory results, medical records)
• Excellent leadership and communication skills (both oral and written)
• Self-motivated, detail and solution oriented, and able to prioritize and plan effectively to meet required deadlines while ensuring high-quality work
• Ability to be flexible, adapt to change, work independently, as well as experience working in a matrix environment.
• Proven ability to collaborate in a team environment and work independently
• Excellent oral and written communication skills
• Must be a team-player, punctual and reliable, dependable and flexible in adapting to change in a multi-disciplinary, fast-paced work environment

TO APPLY, PLEASE EMAIL RESUME TO APPLY@BIOSPlice.COM
NO phone calls please.