Open Position
Study Physician (Medical Monitor)

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 lorcicrivint 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 Study Physician to join our Clinical Development team. The Study Physician will provide medical expertise and have medical responsibility for clinical drug development at Biosplice. S/he will be participant in the design, conduct, monitoring, and data interpretation and reporting of individual clinical studies. S/he will ensure that all clinical studies operate to highest ethical and safety standards in compliance with Good Clinical Practice (GCP) and regulatory requirements.

This individual will contribute to drafting of clinical trial protocols, ICFs, IBs, annual reports, CSRs, and other documents requiring medical input. This individual will also be the primary medical monitor for multiple clinical studies and contribute to/provide medical review, analysis, and interpretation of clinical trial data.

This person will collaborate with various internal (Clinical Operations, Regulatory, Quality, Medical Affairs, R&D, Marketing, Biostatistics) and external experts or agencies to assist in clinical development.

This is a full-time position in the company’s San Diego headquarters. Specific responsibilities of the position include:

- Serves as medical monitor for clinical studies including defining and planning medical monitoring support. Performs review, assessment, and interpretation of critically relevant data for consistency, coherency, reliability, and medical “logic.”
- Responsible for ensuring the risk-benefit of a clinical study, ensuring that all clinical studies operate to the highest ethical and safety standards and in compliance with regulatory guidelines and SOPs.
- Provide support to Drug Safety and Pharmacovigilance for safety surveillance activities,
medical review of individual case safety reports and events of clinical interest, and case triage as needed. Present findings at safety review meetings.

- Be the Medical Expert for assigned clinical trials which includes being readily available to investigators and project team to advise on trial related medical questions or problems during the conduct of the trial.
- In conjunction with other team members and functions, responsible for ensuring appropriate conduct of clinical studies consistent with GCP.
- Participate in all reviews (coding, protocol deviation, etc.) and procedures required for study conduct and database lock.
- Produce relevant material and provide specific medical/protocol training for investigators (Site initiation visit, Investigator meeting, etc.) and Biosplice study team members (CRAs).
- Assist in writing of clinical (study protocol, ICF, IB) and regulatory documents (CSR, DSUR, annual safety reports, IRB responses) in collaboration with the medical writing and clinical teams.

Requirements:

- MD Degree strongly preferred: Graduate of recognized school of medicine
- Three or more years of clinical trials and drug development experience in pharmaceutical industry or CRO preferably in a medical monitoring role
- Experience in musculoskeletal space preferred but all therapeutic areas will be considered.
- Good presentation and communication skills
- 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@BIOSPICE.COM

NO phone calls please.