CoNCERT Pharmaceuticals Inc.®

Title: Senior Clinical Scientist

Job Summary:

Reporting to the Senior Director, Clinical Development, the Senior Clinical Scientist will be responsible for the planning and execution of Phase 1 clinical studies and supporting clinical development programs across multiple indications.

Responsibilities:

- Direct responsibility for the design and planning of Phase 1 studies and protocol development
- Direct oversight of all aspects of study conduct, including site/CRO selection, study start-up activities, preparation of study materials, clinical operations, and data tracking and management.
- Work with CRO and clinical sites to answer protocol-related questions and resolve study conduct and design issues
- In collaboration with study statistician, develop the Statistical Analysis Plan
- Thoroughly review clinical trial data (TLFs) and draft clinical reports provided by external vendor to ensure timely finalization of high-quality study reports
- Responsible for budget negotiations and management of assigned projects and approval of invoices
- Review and summarize clinical trial data and prepare presentation materials as needed for internal meetings and scientific/medical conferences
- Contribute to clinical development plans, clinical sections, and program/study related documentation (regulatory agency briefing documents, INDs, Annual Reports, Investigator's Brochure, Scientific Rationales/Justification, SAPs, Clinical Study Reports)
- Collaborate with a cross-functional team to meet the clinical goals of the drug candidate program
- Contribute to drafting manuscripts and other publications
- Travel as needed

Qualifications:

- PhD/PharmD with strong clinical trial and data analysis and interpretation skills
- 5-8+ years direct clinical trial experience in industry, with direct experience in designing and conducting Phase 1 studies (Phase 2 trials a plus)
- Excellent written and oral communication skills
- Strong leadership, interpersonal, organizational and multi-tasking skills
- Roll up your sleeves/hands-on work ethic
- Excellent attention to detail and problem solving skills
- Independently motivated and strong team player
- Ability to get project/task to the next step in an efficient manner
- Knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials
- Knowledge of Clinical Pharmacokinetics/Pharmacology a plus

If you would like to be considered for a job on the Concert team, send your resume in the body text of an e-mail (no attachments please) to: careers@concertpharma.com.

Concert provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.