CoNCERT Pharmaceuticals Inc.

Title: Associate Director/Director, Clinical Development

Job Summary:
The Associate Director/Director, Clinical Development will support development strategies for drug candidates and execute clinical trials

Responsibilities:
- Contribute to the development of the clinical study design and writing of the study synopsis and protocol
- Initiate interactions with KOLs in specific therapeutic indication to help determine study designs, tractable endpoints and important inclusion/exclusion criteria; plan and lead advisory boards as needed
- Contribute to clinical development plans, clinical sections and review of program/study related documentation (regulatory agency briefing documents and responses to questions, INDs, Annual Reports, Investigator's Brochure, Scientific Rationales/Justification, SAPs, Clinical Study Reports, etc.)
- Contribute to and oversee all aspects of Clinical Operations including collaborating with cross-functional internal teams/departments and external parties for development and management of project timelines and deliverables according to company objectives
- Responsible for budget management of assigned projects, including vendor/site selection, budget negotiations, and approval of invoices
- Work with CRO and clinical sites to answer protocol related questions, resolve study conduct and design issues
- Lead the development/participation/coordination of Investigator Meetings, and contribute to/participate in Study Initiation Visits, study team training sessions as needed
- Attend scientific meetings to stay current on new developments within relevant areas
- Involved in analysis of data for regulatory submissions, publications and study designs
- Review, summarize and present clinical trial data, prepare presentation materials as needed for internal meetings, Business Development, and scientific/medical conferences.

Qualifications:
- MS/PhD/PharmD with strong Science background
- 7-10 years clinical research/management experience in industry
- Hands on experience in designing and conducting Phase 1-3 studies
- Strong knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials
- Strong leadership, interpersonal, organizational and multi-tasking skills
- Excellent written and oral communication skills
- Roll up your sleeves/hands-on work ethic
- Excellent attention to detail and problem solving skills
- Independently motivated
- Ability to get project/task to the next step in an efficient manner
- Capable of changing direction quickly if needed
- Strong team player
- Travel as needed

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 is an Equal Opportunity Employer (EOE). M/F/D/V