Director, Clinical Science
Remote

Summary
Reporting to the Vice President, Clinical Development, the Director, Clinical Science will be a key contributor to Sierra’s clinical development programs. The Clinical Scientist is responsible for scientific leadership for the planning and execution of clinical studies in order to successfully move programs through the clinical research process in a timely manner, in adherence with GCP, appropriate SOP’s and government regulations. Their responsibilities extend through the development of Regulatory submissions to support product approval.

Responsibilities

- Under the direction and oversight of the VP, Clinical Development and the CMO, design, oversee and/or execute, as needed and as appropriate, key clinical deliverables including document development necessary for study design, activation, conduct and reporting (Protocols, ICFs, IBs, CRFs, SAPs, Clinical Study Reports (CSRs)).
- Be a key contributor of content to Regulatory submissions (INDs, NDAs, MAA etc.) as well as to documents to support Regulatory Authority interactions (briefing books, response documents etc.).
- Work closely with individuals in other functional areas (e.g., clinical operations, project and program management, safety and pharmacovigilance, regulatory and quality, pre-clinical / clinical sciences, manufacturing, finance, contract resources, vendors etc.) in the creation, management, and execution of the clinical development plans, in developing innovative and efficient solutions to medical and scientific clinical trial issues, and ensuring the successful execution and completion of Sierra’s clinical trials.
- Contribute to the development of deliverables required for ongoing study data review process.
- Provide medical and scientific input and generate content for abstracts, posters, presentations and manuscripts.
- Contribute medical and scientific input into the Clinical Development Plans for preclinical and early-stage clinical assets.
- Identify risks, develop risk mitigation plans, and escalate risk mitigation strategies as appropriate.
- Contribute to and optimize an effective KOL and investigator communication strategy, interacting with investigators as warranted to obtain necessary information before, during and after the study.
- Working with other departments, create functional policies and procedures to provide strong and efficient clinical development processes that are appropriate for a matrixed environment.
- Ensure that relevant SOPs are current and complete.
- Assess, recommend, track functional budgetary and staffing needs for medical/clinical aspects of clinical trials, as aligned with the Sierra operating model for Development and associated activities.
• May also assist with other broad or diverse activities as needed, and when appropriate, including Clinical Development activities (e.g., contributing to the development of an IND for a preclinical asset, etc), Business Development activities (e.g., contributing to Search and Evaluation efforts, Diligence, etc), or other non-clinical departmental activities.
• Other related duties as assigned.

Qualifications and Requirements
• Advanced degree such as PhD, Pharm D, MD or equivalent and 5-7 year’s directly related experience in a clinical development-biopharmaceutical environment, or the equivalent combination of education and experience.
• Demonstrated skills and understanding in Phase 1-3 clinical trial design and data interpretation; experience with oncology clinical trials is preferred.
• Knowledge of applicable FDA Code of Federal Regulations, Good Clinical Practices (GCP), ICH Guidelines, is required.
• Familiarity with the drug approval process through NDA or BLA is required; Familiarity with ex-US drug approval process, in addition, is a plus.
• Sufficient content expertise and prior experience to be able to be a key contributor to document development such as INDs, Protocols, ICFs, IBs and in particular to Regulatory submission packages (NDA/MAA,) under the direction and oversight of the VP, Clinical Development and CMO.
• Sufficient scientific knowledge and prior experience to play a lead role in the process of clinical study data review and interpretation
• Proven track record of successfully delivering projects on time, to budget and the required quality.
• Excellent interpersonal, verbal and written communication skills.
• Team player, with the ability to move in a fast paced and dynamic environment
• Ability to build and maintain effective internal and external professional relationships.

How to Apply
To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.