Medical Director – Clinical Hematology-Oncology

Job Summary:

Under the supervision of the Senior Vice President, Clinical Development, the Medical Director plans and executes the clinical study design, protocol development, implementation and monitoring of the company's Phase I/III Oncology/Hematology clinical trials. The position will provide key overall clinical, scientific and/or logistical support to clinical development programs and is responsible for the compliance of the department and the company to regulatory standards and procedures.

Responsibilities:

- Assist in or design, author and/or review clinical study synopses, protocols, amendments, study reports and other study-related documents.
- Discuss study design with investigators and key opinion leaders.
- Provide clinical input for clinical protocol monitoring guidelines and analysis plans.
- Drive clinical interpretation of study data. Track emerging efficacy and safety profile of drugs in on-going clinical trials; inform Clinical Development team of changes in the efficacy/safety and/or risk benefit profiles as they occur.
- Provide input and/or prepare clinical sections of regulatory documents (e.g., INDs, IND annual reports, Investigator's Brochures, CRFs, Informed Consent forms, Statistical Analysis Plans, Data Management edit check specs, clinical supplies package diagrams and labeling).
- Lead or assist in the development of publications – abstracts, manuscripts, slides, etc.
- In collaboration with team members (e.g., Clinical Operations, Data Management), assist in identifying / evaluating / monitoring vendors, monitoring clinical trial conduct/status.
- Assist in database finalization, reviews of study results, results interpretation and CSR's.
- Assist in planning and presentation conduct of investigator meetings and Advisory Boards.
- Assist with field site questions during conduct of trials as needed.
- Present study results, as appropriate, to medical/scientific community at meetings and in published format.
- Coaching and mentoring less experienced Clinicians as assigned.

Requirements:

- Medical Doctor (MD) with experience in malignant hematology and/or solid tumors required; recent experience in lymphoid and/or myeloid malignancies preferred.
- 4-8 year's clinical development experience in the pharmaceutical or biotechnology industry (depending on title or degree)
- Phase I–III clinical trial experience preferred
- Thorough working knowledge / understanding of clinical trial design, methodology and statistical concepts
- Working knowledge of the IND/NDA process
- In depth knowledge of GCP/ICH guidelines
- Strong written and verbal communication skills (fluency in written and verbal English) as well as proven ability to interact with different functional groups, investigators, key opinion leaders and the medical/scientific community.
- Leadership skills including a collaborative and team-oriented approach
- Good organizational, time management and interpersonal skills, proficiency in computer and software skills
- Experience with regulatory submissions is an asset
- Available for some travel, including overnight stays