Job Title: Head of Clinical Operations

Reports to: Executive Vice President, Clinical Development

Responsibilities Overview:
Responsible for leading the clinical operations team and managing CRO partners, executing the clinical development strategy to ensure that all clinical development activities within the company are conducted efficiently, to agreed corporate timelines and in compliance with local and global requirements. We offer an excellent total compensation package commensurate with candidate experience.

Primary Duties and Responsibilities:
- Manage global clinical trials via CROs to ensure clinical timelines are met.
- Procure and oversee outside clinical vendors and consultants as required.
- Implement and manage clinical development plans and programs in order to meet corporate goals and objectives.
- Develop clinical trial protocols and other trial-related documents, and work with other departments and functions to implement clinical trial protocols.
- Ensure operational feasibility of clinical development plans and scenarios, including development of, and management to, timeline, budget and resource requirements.
- Supervise and manage activities of clinical operations personnel.
- Effectively negotiate contracts with consultants, clinical investigators, contract research organizations and clinical sites, as necessary.
- Provide input into the clinical development strategy and plans.
- Provide oversight and continuous improvement of department infrastructure through the development of SOPs, guidelines and the use of technology.
- Conduct consultant/contractor/employee/investigator/site training as necessary.
- Serve as an important interface between Company and key opinion leaders and clinical investigators.
- Make presentations to senior staff members and participate in Development Team meetings.
- Attend scientific and external training meetings as needed.
- Ensure familiarity with new developments in disease indications being studied as well as relevant global guidelines and regulations pertaining to conduct of clinical trials.
- Participate in the review and due diligence of new drug candidate opportunities.
- Manage relationship with corporate partners on studies/programs, as applicable, for clinical operations.
- Other clinical operations activities as required.

Qualifications/Skills Required:
- Bachelor's Degree in related field
- 10+ years clinical research experience in drug development with demonstrated career progression
- Extensive experience managing clinical trials via CRO required
- 5+ years of experience in functional line management
- Ability to manage clinical budgets and interface between CROs, vendors and accounting/finance department to ensure budgetary compliance.
- Must have ability to interpret and understand financial documents related to Clinical Operations.

- Ability to think strategically
- Ability to implement tactical plans from a Clinical Development Plan
- Advanced knowledge of FDA regulations and ICH guidelines regarding GCPs
- Excellent communication, presentation, and interpersonal skills
- Ability to manage directly and indirectly
- Proven ability to actively lead meetings
- Strong ability to influence decisions with stakeholders in Clinical Operations and cross functionally
- Translates complex and broad concepts into plans for action and constructive improvement
- Strong facilitation, organizational, analytical and time management skills
- Effectively use automated systems and computerized applications (e.g., Excel, PowerPoint)
- Demonstrated skills in development of study plans and documentation
- Ability and willingness to travel
- Accountability – self-motivated, results oriented team player who holds him or herself accountable for performance and takes ownership of his/her work.