Job Description

1 Position in the Organization	
Job Title:	Senior Director or Director, Clinical Operations
Department:	Clinical Operations
Manager Job Title:	CMO or designee
GxP Functions:	☐None ☐All GxP ☐GLP ☐GCLP ☒GCP ☐GPvP ☐GMP ☐GDP
Location:	Fort Washington, PA

2 Description

The Senior Director or Director of Clinical Operations is responsible for clinical study planning, execution, timelines and budgets for multiple clinical development programs. These responsibilities include, but are not limited to, vendor identification and selection, preparation of study related materials, relationship management between study sites and vendors; in particular, oversight of CRO(s), study related activities, identification of project risks and contingency planning, as well as ensuring all activities are in compliance with GCP, ICH and other relevant guidances.

3 Duties and Responsibilities

- Lead and manage integrations of all study team activities, leveraging internal resources, expertise and knowledge, along with optimizing CRO resources, expertise and knowledge.
- Provide strategic input and execution of clinical trials from protocol design to the final clinical study report for specified studies.
- Manage all aspects of CRO/vendor identification, request for proposal submission, CRO selection, and the day-to-day operational activities. Leverage resources, expertise, and knowledge within the CRO/vendor for smooth study execution.
- Oversee study operations including: study site selection and regulatory submissions, review of CRO monitor visit reports and site correspondence, drug supply and use, enrolment of subjects, regulatory document flow including informed consents (and translations), study timelines, all budgetary and financial information, performance metrics, data flow, etc.
- Participate in Case Report Form and/or EDC specification design and user acceptance testing, data management plan review, and data quality review and tracking.
- Effectively communicate and interact with Key Opinion Leaders.
- Lead the development of contingency/risk management plans for projects.
- Prepare budgets, timelines, and forecast for clinical studies.
- Interface with development project teams, and the legal and finance departments for planning, execution and tracking of Clinical Trials.
- Collaborate with Clinical, Regulatory, and Quality team members to ensure compliance of department/study activities with FDA regulations, guidelines, and principles of ICH GCP and company SOPs.
- Participate in development and review of Clinical Development processes, systems and initiatives.
- Ability to travel (no more than annual average of 20%).

Job Description

4 Qualifications and Skills

- Bachelor of Science degree in life sciences or other scientific discipline required.
- Minimum of 10 years' experience in Clinical Trial Management required.
- Experience in infectious disease is desirable.
- Demonstrated regulatory knowledge including but not limited to Good Clinical Practices (GCPs), ethics requirements for protection of human subjects, set-up and maintenance of Trial Master Files.
- Proficient with MS Office Suite (Excel, Word and PowerPoint) and MS Project.

5 Competencies

- **Customer-centric & entrepreneurial mindset**. Ability to address issues, communicate, and develop programs, and take on other tasks as assigned with a customer focus based on a foundation of ethics, integrity, and quality.
- **Results-driven individual** with strong levels of perseverance, resilience, and resourcefulness; works toward both individual and team goals. Demonstrates high degree of emotional intelligence, personal initiative/self-leadership, self-motivation and the ability to be involved at various levels and willingness to "roll up sleeves" to drive results and outcomes. Ability to adapt quickly and act with urgency, welcoming change, while producing high quality work with minimal direction.
- **Continuous learner** showing a desire and ability to solve complex business problems and provides innovative, value added solutions.
- **Superior organizational/project management skills**. Demonstrated ability to manage multiple assignments/projects, strict timelines, and to identify project interdependencies, resource needs, potential risks/pitfalls and mitigation plans. Recognized as an integrator and solution provider.
- **Highly collaborative workstyle**; with an ability to see the "big picture' and influence others across businesses, functions, geographies and levels, motivated by collective success.
- **Communicate with clarity both verbally and non-verbally**; be clear, concise, detailed and actionable. Seeks and provides meaningful feedback. Trusted advisor.