Senior Director, Trial Operations

Reports to: VP, Clinical Development

Classification: Exempt

Summary:
Lead the development and implementation of clinical trial operations function. Provide oversight to clinical trial operations team and studies to ensure clinical trials are conducted in accordance with protocols, SOPs, GCPs, and other applicable regulatory requirements. Accountable to ensure trials meet clinical study milestones according to corporate objectives. This role will oversee vendor activities with appropriate risk mitigations and planning.

Essential Functions and Job Responsibilities:

- Contribute expertise in all operational activities pertaining to the execution of clinical trials
- Lead the operational implementation of clinical trials
- Participate in resource allocation, prioritization and budgeting to ensure department goals and milestones are aligned and meet corporate goals and timelines
- Serve as primary contact for functional area team leaders in managing protocol execution
- Comment, review and approve study documents related to trial operations (trial operational plan, monitoring plans, etc.) and other documents as appropriate to the function
- Lead operational strategy meetings to review trial status and progress
- Participate in the development and review of trial and overall clinical program budgets
- Create, manage and take corrective measures as necessary to keep project(s) in line with agreed timelines, quality, budget and performance
- Help develop site recruitment, enrollment and engagement strategies
- Assess impact of project scope changes to understand implications on agreed plans and budgets
- Analyze ongoing risk assessments with accompanying mitigation plans and contingency plans
- Manage interdisciplinary activities to ensure clinical operations team collaborates effectively to set achievable goals, milestones and timelines
- Identify and implement best practices and process improvements
- Ensure trial adherence to ICH, GCP and local regulations
- Maintain strong vendor interactions and collaborations, including hands-on management and interaction
- Complete other responsibilities as assigned

Minimum Qualifications:

- BS/MS/doctorate degree in scientific discipline or equivalent
- Minimum of 10 years of clinical operations experience in the pharmaceutical industry
- Minimum of at least 5 years of direct line management experience and vendor management
- Thorough understanding of the process of operational execution of a clinical development trials and program (clinical trial design, implementation, management and reporting)
- Strong ability to problem-solve and diagnose the issue and implement appropriate corrective actions
- Knowledge of the drug development process and laws and regulations affecting the pharmaceutical industry

- Knowledge of the policies, key personnel and regulatory climate at the FDA and other global health authorities
- Experience developing trial plans including site monitoring strategies, risk mitigation strategies, trial budgets and site selection
- Experience managing contractors and maintaining vendor relationships
- Excellent written and oral communication skills with the ability to communicate clearly to all organizational levels