Clinical Trial Manager

Reports to: Associate Director of Clinical Operations

Classification: Exempt

Summary:
Oversee the conduct of all clinical studies performed and ensure studies are completed on time within budget and in compliance with SOPs, FDA regulations and ICH/GCP guideline.

Essential Functions and Job Responsibilities:

- Implement and execute clinical programs, including development and administration of site budgets
- Assist in the writing of protocols, the design of case report forms and other study documents and forms
- Work closely with external site monitors to oversee all aspects of clinical trial
- Evaluate, tabulate and may prepare written summaries of clinical data
- Ensure compliance with protocol, overall clinical objectives and FDA requirements
- Conduct review and source verification of clinical data and ensure timely resolution of data queries
- Maintain contact with clinical investigators and staff
- Primary interface with CRO
- Manages communications between monitors and clinical sites and CRO
- Tracks all required site documentation
- Complete other responsibilities as assigned

Minimum Qualifications:

- Requires a BS, MS or equivalent in life sciences, or related technical degree with 8+ years of experience
- Experience managing multi-site trials
- Experience in Clinical Trial Management, specifically demonstrating application of research methodology in a phase 1 and phase 2 clinical setting
- Thorough knowledge of GCP requirement
- Excellent written and oral communication skills and ability to operate well in a team environment