JOB DESCRIPTION

POSITION TITLE: Clinical Trials Manager **DEPARTMENT:** Clinical

OBJECTIVE: The Clinical Trials Manager will 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 BASIC DUTIES:

- 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.

QUALIFICATIONS

EDUCATION:	Requires a BS, MS or equivalent in life sciences, or related technical degree with 8+ years of experience.
EXPERIENCE REQUIRED:	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.
REQUIRED KNOWLEDGE:	Thorough knowledge of GCP requirement.
SKILLS/ ABILITIES:	Excellent written and oral communication skills and ability to operate well in a team environment

SUPERVISORY RESPONSIBILITY

May supervise administrative support and other clinical staff

WORKING CONDITIONS

Primarily works within a general office setting. May be required to travel to clinical sites occasionally.