Job Title: **Sr. Clinical Project Manager**

Reports to: **Director, Clinical Operations**

DESCRIPTION:

- Manage global clinical study teams, CRO's and Vendors to ensure that the study(ies) are completed on time, within budget, and in compliance with SOPs, FDA regulations and ICH/GCP guidelines
- Lead on one program and support on a second program
- Manage clinical operations personnel supporting assigned programs
- Mentoring of junior staff

EXPERIENCE AND QUALIFICATIONS:

- At least 8+ years of relevant clinical experience in the pharmaceutical industry or equivalent with 6+ years as a CRA in biotech or Pharmaceutical clinical operations environment, and 3 years prior experience as a CPM or higher level
- 1+ years managing staff/direct reports
- Must be hands on and used to a start-up environment
- Knowledge of GCP and ICH guidelines required
- Proficiency in the implementation, monitoring, and management of clinical trials
- Able to work collegially within a team and carry out duties/responsibilities with general instructions
- Proficiency with MS Word, Excel, Outlook, PowerPoint and Microsoft Project
- Experience with giving presentations
- Study start-up experience required
- Demonstrated track record in the oversight of all trial operational aspects including: budgets, timelines, resources, vendor selection and management, oversight of clinical team staff during study start-up, interim monitoring and closeout activities

Other duties and assignments as required for the overall success of studies. Duties may change based on the current status of clinical programs and current company needs.

Skills:
Excellent verbal and written communication skills. Excellent organizational, record retention, time management, decision making, customer service, and interpersonal skills. Good command of written and spoken English language
Experience managing large clinical studies and working with CROs required
Ability to travel domestically as required (up to 35%)

Education:
BS/BA, RN, or equivalent with at least 8+ year's clinical trial monitoring / clinical trial and vendor

management experience in accordance with CFR, GCP and ICH Guidelines, proficiency with Microsoft Office (Excel, Word, PPT, etc.)