

## Clinical Affairs Associate

**Provides clinical research study expertise and support.**

### **Duties and Responsibilities:**

- Assist in identifying skilled and appropriate study investigators.
- Monitoring progress throughout study.
- Anticipate and solve issues that arise during the course of a clinical study.
- Assist with designing study materials and coordinating TMFs.
- Provide clinicians instructions in support of conducting a clinical study.
- Collection and authentication of data collection forms.
- Writing reports and review of CSR and study sub-reports.
- Assist clinical affairs team in execution of data generating projects, including focused analysis of existing datasets and medical team generated clinical research.
- Support company goals and objectives, policies and procedures, Good Clinical Practices, and FDA/MDD regulations.

### **Skills/Qualifications/Competencies:**

- BS in Science or healthcare field required.
- Minimum of 2 years clinical trial related experience in the pharmaceutical, biologics, and/or medical device industries.
- Ability to assist with managing the clinical trial remotely including multiple site locations.
- Manage all projects while balancing company risk at each step
- Strong verbal and written communication skills and interpersonal skills.
- Strong attention to detail, ability to work within the quality management system and with all levels of the CRO.