POSITION TITLE: CLINICAL STUDY MONITOR
LOCATION: SECAUCUS, NJ

Responsibilities:

- Ensure the Sponsor, Investigator, and study team adhere to current FDA regulations, applicable ICH/GCP guidelines, local policies and standard operating procedures.
- Adhere to monitoring plan protocols; e.g. monitoring visit type, frequency, and required critical monitoring activities by utilizing monitoring tracking forms and other monitoring related tools and templates.
- Monitor clinical trial progress through a combination of data review and on site monitoring visits.
- Verify that trial data is consistent with patient clinical notes and other source documentation (source data verification/review).
- Independently coordinate ongoing and upcoming monitoring assignments
- Meet expected timelines for completion of monitoring activities and submission of written monitoring reports.
- Assist in the development and writing of clinical trial monitoring plans.
- Provide recommendations and guidance to study specific monitoring teams and assist in audit readiness and preparation.
- Participate in regular monitoring team group meetings.

Requirements:

- Bachelor's degree in a related health profession or a field related to research compliance
- 3+ years of clinical trial study experience with 2+ years of monitoring experience
- Knowledge of ICH guidelines, GCP, and the clinical trial study process
- Ability to work effectively in teams as well as independently
- Strong verbal and written communication
- Ability to manage multiple projects at a time