



## **Position: Biostatistician**

### **Job Description:**

The Biostatistician performs biometrics and SAS programming activities for all clinical trials involving drugs, biologics and devices, and oversees the activities of programming and biostatistician consultants.

### **Responsibilities:**

- Develops statistical section in clinical trial protocol
- samples size and statistical power calculations
- Generates randomization schedule according to the protocol
- Develops Statistical Analysis Plan with input from project team and sponsor per SOPs and WPDs
- Consults on other statistical tasks, such as support for CRFs development and study report writing
- Performs SAS programming to generate tables, listings, figures, and statistical analyses
- Develops SAS programs to build standard tabulation datasets and analysis datasets according to certain industry standard or the format requested by client
- Oversees validation and quality assurance aspects of control over SAS program content, documentation and archiving of programs
- Ensures adherence to timelines for the biostatistical and SAS programming aspects of projects
- Performs other duties assigned by supervisor

### **Education and Experience**

- Bachelor's degree in Medical Statistics or related subjects, advanced degree (M.S. or Ph.D.) preferred
- Minimum one year of experience in use of statistics as applied to drug or medical device development.
- Knowledgeable in all aspects of the Federal (FDA) regulations and requirements governing the conduct of drug and device studies including, but not limited to, GCP and ICH requirements
- Demonstrated skills in team-building and the ability to work successfully in a team environment.
- Good command of English skills including reading, writing and speaking
- Demonstrated computer skills including MS Office and Internet usage.