Our growing company is hiring for a manager, statistical programming. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for manager, statistical programming

- Participates on multidisciplinary project teams
- Consistently achieves individual goals as set with manager
- The Statistical Programming effort provides a major component of the statistical summarization of each clinical study and of the accumulated data supporting a new drug candidate as it reduces the volume of data to concise data listings and summary tables needed to interpret the results
- FDA regulations require the submission of data files, data listings, and summaries in electronic formats
- SAS is the only format currently accepted by FDA for the submission of the data
- Provide ongoing supervision, advice and consultation to the Lead Programmers and the rest of the programming team to ensure timely and efficient completion of projects
- Provide input and review of new business proposals, including time and cost estimates and associated documentation
- Work as a statistical programmer on drug development project teams
- Programming of ad hoc requests for exploratory analyses and time-sensitive deliverables
- Identify and establish secured computing/analytical environment, programming standards and practices to ensure alignment between programming strategic direction and company's R&D strategies

Qualifications for manager, statistical programming

- Knowledge of relevant internal and external standards and guidance for clinical development (CDISC, EMEA/FDA, ICH- GCP)
- In-depth knowledge of applicable clinical research regulatory requirements
- Master's degree in computer science or related field and 5 years relevant experience including 1 year in a leadership capacity
- In-depth knowledge in industry data standards and regulatory data submission requirements, with a focus on ADaM data standards and eSub data package
- Candidates must demonstrate thorough knowledge of SAS by successful completion of the SAS core certification test for version 9 SAS (SAS Certified Professional V6) or an equivalent means