Esperion
The Lipid Management Company

Company Overview

Esperion is a small company doing big things. Our innovative team of lipid management experts are committed to leveraging our understanding of cholesterol biosynthesis to develop innovative therapies for the treatment of patients with elevated low-density lipoprotein (LDL-C). At Esperion we are passionately committed to bringing complementary therapies to the hypercholesterolemia space that address unmet patient needs in a way that is "patient-friendly, physician-friendly and payer-friendly."

Esperion's corporate headquarters are located in Ann Arbor, MI. The Company offers a competitive salary including a performance-based bonus program and stock-based compensation, a comprehensive benefits package including a 401(k) matching plan and health insurance, and paid time off and holidays.

Position Title: Principal Programmer

Designs, develops, evaluates and modifies computer programs to analyze and evaluate clinical data. Ensures the analysis and presentation of clinical data is accurate and complete. Provides project team leadership for vendors. QA/QC of vendor's outputs. Adherence to Esperion Policies, SOPs and other controlled documents. Provides statistical programming technical support for internal cross-functional teams including clinical, data management, medical writing, publishing and regulatory affairs. Provides support for NDA/MAA filing and response to regulatory agencies' questions.

Preferred Location: US-Remote

Essential Duties and Responsibilities*

- Write, test and validate software programs in Unix to produce analysis datasets and presentation output, to be included in reports for submission to regulatory agencies, publications and other communications
- Efficiently manage project timelines
- Review and approve key study-related documents produced by other functions, e.g. SAPs, CRF, Data Management Plan, NONMEM specifications, etc.
- Write, and/or review and approve programming plans
- Write, and/or review and approve analysis dataset specifications
- Oversee CRO programmer counter parts
- Review and ensure CDISC standards of study data submission packages
- Review and ensure quality submission reviewers guides and define documents
- Represent the programming function and participate in multidisciplinary team meetings
- Write, test and validate department-, product- and protocol-level macros and utilities
- Participate in study and systems audits by Clinical Quality Assurance (CQA) and external bodies, and respond to audit questions and findings
- Interview potential programming candidates
- Provide input to and participate in intra-departmental and clinical meetings
- Support and mentor junior programmers

**additional duties and responsibilities not listed here may be required*

Qualifications (Education & Experience)

- BS degree in computer science or related field with a minimum of 5 years of biotech or pharmaceutical industry experience required; MS degree in computer science or related field preferred; or equivalent combination of education, training and experience.
- Experience leading SAS programming projects in the pharmaceutical industry demonstrated by the ability to independently act as the point of contact on the statistical programming for all phases of clinical trials.
- Proficient in industry standards, medical terminology, and clinical trial methodologies.
- Advanced knowledge in Base SAS, SAS/STAT, SAS Graph and SAS Macro Language
- Following the Study Data Tabulation Model (SDTM) Implementation Guide, writes specifications for SDTM datasets.
- Following statistical analysis plans and the Analysis Data Model (ADaM) Implementation Guide, writes specifications for analysis datasets.
- Understands and conducts work consistent with GCP, ICH, 21 CFR part 11, internal SOPs and training, and international regulatory requirements.
- Understanding of Electronic Submissions
- Proficient in CDISC implementation of SDTM and ADaM standards.
- Recent NDA or BLA submission experience preferred.
- Timeline & deliverable management for programming outputs

All qualified applicants are requested to submit a cover letter and CV via email to hr@esperion.com.