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: Head of Biometrics

The Head of Biometrics will lead the biometrics group consisting of data management, statistical programming, and biostatistics. This role will be responsible for leading the biometrics strategy for the company, preparation and presentation at all key regulatory body meetings (including an FDA Advisory Committee), ensuring proper day-to-day oversight of biometrics vendors, and leading the biometrics aspects of global Marketing Applications including New Drug Applications/Marketing Authorisation Applications in a fast-paced environment.

Preferred Location: Remote - US

Essential Duties and Responsibilities*

- Oversee operations and management of the functional areas of global statistics, statistical programming, and data management
- Sponsor oversight for:
    - Contract Research Organization (CRO) deliverables
    - Maintain Statistical Analysis Plans (SAPs) and mock updates, as needed
    - Review SDTM spec and data sets
    - Review ADaM spec and data sets
    - Draft Table Figures and Listings (TFLs) (BDR) review with team
    - Data Monitoring Committee deliverables for ongoing Phase 3 studies
    - DSUR TFLs
    - Pre-database lock data review
    - BIMO package preparation
    - Top line results review/press release preparation
    - Oversee the Day 120 Update to FDA in support of NDA
    - Regulatory Information Requests
- Support planned and adhoc analyses on post-trial readouts for business development needs, as well as publications and presentations for Phase 3 trials

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Essential Duties and Responsibilities Continued*

- Submissions work on ISS and ISE
    - iSAP development in collaboration with internal SMEs
    - CRO oversight to implement iSAPs including creating CDISC datasets and analyses
    - Regulatory interactions including: planning, briefing document, meetings, and response to questions
    - Integrated analysis dry run
    - Coordination with CRO for data transfer
    - GAP analysis for all completed studies
    - BIMO dataset and listings
- Participant and key player for key regulatory meetings including Advisory Committee Meetings as a participant (speaker, where needed) and Oral Explanations. Oversee statistics and data management team relative to Advisory Committee needs.
    - Generation, oversight of all statistics and data management deliverables for Marketing Applications. Statistical reviewer for Marketing documents and Information Requests.
    - Key participant in Global Regulatory Health Authority Meetings for Biostatistics
- Meet all internal cross functional deliverables
    - CRF review, RAVE UAT, external data transfer plan
    - CSR review
    - IB/DSUR/regulatory documents review
    - Protocol deviation review

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

Qualifications (Education & Experience)

- Master's degree in statistics, biostatistics, epidemiology or other relevant scientific discipline required; Ph.D. preferred.
- A minimum of 15 years of experience in the pharmaceutical or biotechnology industry
- Prior Large Submission Experience required
- Experience preparing and presenting at Advisory Committee a plus
- Ability to work with highly aggressive timelines
- Ability to proactively manage vendors against challenging timelines
- Prior management experience required.
- Extensive knowledge of clinical trial development and statistical methodology related to trial design and conduct of clinical studies is required; experience in CV or lipids is preferred
- Good knowledge of ICH, FDA, and GCP regulations and guidelines; strong well-rounded technical skill, SAS, SDTM, ADaM and CDISC
- Has scientific background and understanding of clinical trials, clinical development operations and regulatory compliance
- Experience with regulatory agency (FDA and EMA) interactions
- Experience with NDA and/or MAA submissions, including development of integrated analyses of efficacy and safety
- Excellent oral and written communication skills and clear presentation skills

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