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: Medical Monitor

The Medical Monitor will serve as the medical expert for assigned clinical trials. This role will provide input into the design and conduct of clinical trials, assessment and interpretation of safety data, and contribute to investigator training. Available as a remote position from a home based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- Further Esperion's clinical development program by assisting in the design and conduct of clinical trials including the drafting of protocols and amendments.
- Be the Medical Expert ("Medical Monitor") for assigned clinical trials which includes being readily available to advise on trial-related medical questions or problems during the conduct of the trial.
- Contribute to investigator training.
- Take a lead role in drafting the Integrated Summary of Safety and Integrated Summary of Efficacy
- Assist in medical review, assessment and interpretation of clinical and safety data to ensure that the data are correct and presented with the appropriate medical interpretation.
- Lead medical aspects of medical monitoring. Work closely with the Pharmacovigilance and Safety representatives providing medical input into safety reports including, SAE narratives and analysis of similar events, Development Safety Update Reports (DSURs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) reports, Company Core Safety Information (CCSI), Investigator Brochure (IB), Risk Management Plans, Integrated Summaries of Safety and Efficacy, Clinical Study Reports and preparation of labels.
- Responsible for medical monitor expertise input into the development and implementation of standard operating procedures for all aspects of Adverse Event report handling, aggregate reporting and assuring compliance with global and local regulatory requirements.
- Attendance at teleconferences and face-to-face meetings with global regulators. Responsible for implementing alignment across policies/procedures and ensure that data generated meet monitoring and compliance with FDA, ICH guidelines and GCP.

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

-continued on page 2-

Qualifications (Education & Experience)

- Medical degree with strong leadership skills including 5-10 years direct experience in the pharmaceutical industry preferably in a medical monitoring role.
- US and EU experience preferred.
- Experience in lipid lowering and/or cardiovascular space preferred but all therapeutic areas will be considered.
- Understanding of local and global drug safety regulations and processes and clinical trial oversight, including global GCPs.
- Experience providing input into key regulatory documentation.
- Excellent interpersonal and communication skills with ability to relate to both internal and external stakeholders.
- Strong communication and presentation skills as well as an ability to communicate clearly and concisely in writing.
- Experience presenting to a wide variety of audiences including internal teams and medical/scientific communities
- Experience using medical monitoring software such as JReview or Spotfire.

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