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: Director, Clinical Development

The Director, Clinical Development, will manage the development and execution of clinical trial plans in coordination with the clinical operations team. Responsibilities may include: study design and protocol development; medical monitoring support; data review, summarization and interpretation; and drafting of regulatory documents. Available as a remote position from a home-based office.

Preferred Location: Remote - US

Essential Duties and Responsibilities*

- Design clinical studies and write synopses, protocol and amendments. Support and provide input into the preparation, initiation, and execution of clinical studies in compliance with project plans, federal regulations, and GCP.
- Provide support for medical monitoring of assigned clinical trials by answering eligibility questions related to the protocols and supporting line listing reviews.
- Contribute to investigator training.
- Work closely with the Safety team representatives providing input into safety reports including SAE narratives, Development Safety Update Reports (DSURs), Suspected Unexpected Serious Adverse Reactions (SUSARs) reports, Company Core Safety Information (CCSI), Investigator Brochure (IB), and Risk Management Plans.
- Summarize data and contribute to Clinical Study Reports.
- Support drafting of regulatory documents as required. 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*

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Qualifications (Education & Experience)

- MS in Sciences or equivalent combination of education and applicable job experience. PhD, MD or DO degrees are preferred.
- Minimum of 10 years of clinical development experience in the pharmaceutical or biotechnology industry.
- Experience in Nonalcoholic Fatty Liver Disease and/or Nonalcoholic Steatohepatitis space required
- Extensive experience with compliance issues and strong understanding of FDA regulations, GCP and/ SOPs in clinical research within a pharmaceutical or biotech environment.
- Experience providing input into key regulatory documentation. Face-to-face interaction experience with FDA preferred
- Strong communication and presentation skills as well as an ability to communicate clearly and concisely in writing.

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