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 Pharmacology

The Director of Clinical Pharmacology will provide subject matter expertise to support the continued clinical development of the Company's lead candidate molecules across all phases of development. This role will represent the Company from a clinical pharmacology perspective and provide expertise in clinical pharmacology related matters with regulatory authorities. This position has the opportunity to work remote, from a home-based office.

Preferred Location: Remote - US

Essential Duties and Responsibilities*

- Responsible for providing clinical pharmacology expertise on protocol design, clinical study reports, investigator brochures, periodic safety updates (DSURs or PSURs), and provide scientific expertise in the preparation of clinical pharmacology sections in various regulatory submissions globally.
- Provide subject matter expertise to support the continued clinical development of the Company's lead candidate molecules.
- Participate in interdepartmental scientific and clinical activities specific to implementation and conduct of clinical protocols.
- Work with various in-house functional groups with regards to studies design issues including, pharmacokinetics, drug-drug interactions, and interpretation of ADME studies.
- Direct and/or manage clinical pharmacology function to ensure adherence to study protocols, regulatory and internal operating procedures, intended timelines and the budget.
- Provide subject matter expertise in pharmacokinetics data analysis, interpretation and risk assessment on drug candidates in development.
- Develop strategies for pharmacokinetic analysis in clinical studies, population modelling, dosing and labelling recommendations.
- Effectively communicate clinical project updates to the Executive Leadership Team and appropriate functional groups.
- Provide expertise in clinical pharmacology related matters with regulatory authorities including response to questions from regulators, teleconferences, Face-to-face Meetings, Oral Explanations, etc.
- Provide clinical pharmacology expertise for core drug labelling and approvals.
- Provide training and education to internal staff and external vendors, sites and investigators.

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

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Qualifications (Education & Experience)

- PhD in Pharmacology or Pharmaceutical Sciences or related Sciences or equivalent combination of education and applicable job experience; MD or Pharm. D with relevant experience will be considered
- Minimum of 8 years of relevant experience in the pharmaceutical or biotechnology industry. Extensive experience with regulatory requirements, preparation of the clinical pharmacology sections of NDAs, BLAs, understanding of FDA regulations, GCP and/ SOPs in clinical research within a pharmaceutical or biotech environment or relevant
- Clinical pharmacology expertise, particularly for study design and data interpretation, risk assessment necessary for preparation and filing of INDs, original and supplemental NDAs.
- Subject matter expertise in Clinical pharmacology, drug interactions and ADME, bioanalytical needs, and risk assessment.
- Experience interacting with the FDA and/or EMA on INDs, NDAs, BLAs, and development programs.
- Ability to provide scientific and clinical guidance to Clinical Trials Management, Biostatistics and Data
- Management Drug Safety, Regulatory and Project Management to meet project deliverables and timelines.
- Expert in clinical pharmacology study design (e.g., multiple arms, crossover, double blind, and multi-center), in all phases of pre-approval clinical trials.
- Good understanding of regulatory guidelines for ADME, DDI, dosing and labelling recommendations
- Demonstrated ability to work in a matrix leadership environment
- A proven ability to work effectively with multiple departments.

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