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: Senior Medical Writer

The Senior Medical Writer will participate in the management and writing of required written documentation for key regulatory projects, as well as, nonclinical, clinical, and pharmacovigilance documents. Available as a remote position from a home-based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- Manages and writes required written documentation for key to regulatory projects as part of regulatory submissions such as IND's, NDA's and MAA's (Module 2 components), briefing documents, pediatric plans, and responses to regulatory questions.
- Manages and writes nonclinical, clinical , and pharmacovigilance documents including:
    - Prepares clinical documents such as protocol amendments, clinical study reports, investigator brochures, etc.
    - Prepares nonclinical documents such as nonclinical study reports;
    - Reviews data as part of document preparation and contributes to the strategy and planning for data presentation.
    - Analyzes and interprets company data and published data in order to be savvy in the therapeutic area;
    - Participates in the preparation of abstracts, posters and presentations for scientific meetings and congresses.
    - Supports writing aspects of pharmacovigilance documents such as Development Safety Update Reports and Risk Management Plans.
- Collaborates closely with cross-functional teams: clinical, nonclinical and regulatory teams

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

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Qualifications (Education & Experience)

- Solid experience in strategic regulatory writing and pharmaceutical writing including interpreting clinical data and writing concise company positions
- Experience required with writing and leading regulatory documents to support US and global regulatory submissions
- Strong communication and collaborative skills with experience and comfort working in a very fast-paced virtual corporate environment with cross-functional team members
- BS with 8+ years or MS with 5+ years of medical writing in the pharmaceutical and/or biotechnology industry required.
- Experience as a medical writer with large regulatory submissions (NDA's).
- Preferred qualifications include sub-specialty training in therapeutic areas of relevance to cardiovascular medicine and lipid disorders.

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