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, Regulatory Labeling

The Director of Regulatory Labeling is a strategic role leading the development of approved product labels for Esperion Therapeutics. Responsibilities include developing the strategy for labeling content, maintaining the Company Core Data Sheets, Prescribing Information, Patient Labeling, and Instructions for use. The incumbent will be responsible for providing regulatory compliant, competitive, and up-to-date labeling; regulatory labeling leadership; strategic regulatory labeling health authority interactions, ensuring the execution of regulatory labeling are aligned with the regulatory strategy and corporate goals, and the management of all vendors contributing to the labeling objectives. Available as a remote, work from home opportunity.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Providing regulatory strategic guidance and oversight to all labeling activities
- An active member on regulatory and development teams responsible for identifying requirements to ensure labeling claims support the regulatory plans and are in-line with corporate goals.
- Lead the labeling teams.
- Ensuring commercial product labeling is compliant with worldwide regulations.
- Create and lead the development of labeling processes.
- Provide strategic input on interpretation and implementation of key regional labeling regulations, guidelines, and best labeling practices, and align with global strategic labeling plan.
- Responsible for labeling negotiations and health-authority interactions
- Guide/support all labeling related negotiation meetings or teleconferences, as needed.
- Lead or direct the creation of high quality documents supporting changes to the company core data sheet or local labeling with internal and/or external experts.
- Review appropriate summary documents to ensure the labeling message is consistent with the overall representation of a marketing application.
- Guide launch teams on launch strategy for new products.

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

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Qualifications (Education & Experience)

- Bachelor's degree in a scientific discipline. Advanced degree preferred.
- Minimum of 10 years of industry experience with at least 4 years in a global labeling.
- NDA and MAA labeling submission experience
- Proven successful track record in US and global regulatory labeling submissions for products in development and commercial products.
- Demonstrated experience negotiating with internal and external stakeholders on complex regulatory issues.
- Strong knowledge and understanding of regulatory labeling requirements and strategic labeling planning.
- Experience working cross-functionally and with all levels of management.
- Excellent written and oral communication skills.
- Regulatory experience with Cardiovascular therapeutic area preferred.

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