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: Manager, Global Regulatory Affairs

The Manager of Global Regulatory Affairs will be responsible for supporting the life cycle management of our NDA and MAA. This role will coordinate the compilation of all the documents needed and review from a regulatory perspective to ensure strategy alignment, formatting, and flow are correct and appropriate. Available as a remote position from a home-based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- Leads and develops regulatory strategy submissions (including IND's and marketing applications) that is reflective of applicable US, EU and other regional requirements acceptable for submission to global regulatory competent authorities (i.e. FDA, EMA), generates strategies, assesses risks and develops contingency plans.
- Experience leading or supporting regulatory interactions in a global arena (especially US).
- Acts as a regulatory representative to support cross functional team; accountable for assigned projects and activities, independently completing work within assigned work group/project teams, for multiple projects.
- Interprets regulatory requirements, develop strategies (including novel approaches), assess risks and develops contingencies.
- Accountable for assigned programs, managing day-to-day delivery of plans/submissions and strategic activities for specific assigned projects.
- Ability to operate independently, virtually, and as a leader to resolve complex issues and manage regulatory risks and ambiguous situations within project teams with support from line management.
- Responsible for the development and preparation of regulatory documentation, may act as a primary writer/editor or coordinator, coordination and management of global submissions (including but not limited to IND's, IMPD's, NDAs, MAAs, Response to Questions, Expedited Program Applications, Orphan Applications, etc.).
- Ability to collaborate effectively across a network of stakeholders, partners, customers contract research organizations (CRO's) to deliver high quality submissions.

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

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Qualifications (Education & Experience)

- Bachelor's degree in scientific discipline; advanced degree preferred.
- At least 5+ years of previous industry experience in a strategic regulatory role.
- Regulatory Submissions, preparation and strategy in the US with diverse experience in leading and developing the strategy for multiple submission types including large submissions with intimate knowledge of the electronic Common Technical Document (i.e. IND's, NDA's).
- Strong Regulatory writer and reviewer for key documents such as response to questions, meeting requests, briefing documents, Module 2, Module 1 documents.
- Familiarity with regulatory operations, publishing and submissions preferred;
- Recent experience win the development and therapeutic areas of lipid drugs in the a US is a major plus.
- Excellent written and verbal communication skills (native and non-native English speakers) with the ability to meet regulatory requirements; develop strategies while maintaining effective relationships.
- Ability to lead, drive, communicate effectively, establish and maintain productive working relationships, and influence peers and others within the organization.
- Strong organizational skills and high level of attention to detail, with the ability to coordinate multiple large and diverse projects simultaneously.
- Ability to be highly driven and self-sufficient.
- Ability to wear multiple hats and work in a small company and virtual company fast-paced environment.
- High integrity with respect to maintenance of proprietary, confidential information.
- Strong decision-making and problem-solving skills.
- Composure under pressure.

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