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 Manager/Associate Director, Global Regulatory Affairs

The ideal candidate is a global regulatory content expert and will develop global regulatory strategies for assigned projects and provide strategic guidance to the drug development team(s) to ensure timely and successful implementation. This position reports to Director Global Regulatory Affairs. Available as a remote position from a home-based office.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Serve as a key player on the Global Regulatory Strategy team in early and late stage development and for large global regulatory submissions.
- Lead or support development and implementation of regulatory strategies, including risk assessment and mitigation plans, using knowledge of applicable US, Europe and other regional regulatory requirements to obtain marketing approvals.
- Lead or assist in the creation and submission of internal and external regulatory documents, e.g., regulatory strategy plans, regulatory correspondence, CTAs, INDs, MAAs, NDAs, variations, and supplements and other relevant regulatory submissions.
- Author regulatory documents, such as response to health authority questions, meeting requests, briefing documents, Module 1, and Module 2 documents.
- Through flexibility and creativity, think through problems in a focused, resolution-oriented manner, and help team(s) resolve complex issues.
- Independently develop regulatory intelligence to support program activities.
- Accountable to know therapeutic landscape and regulatory history in order to ensure that the strategic direction is sound and in line with current affairs.
- Use influence effectively across a network of stakeholders, partners, customers, and contract research organizations to deliver high quality submissions on time.
- Provide regulatory guidance and input to other colleagues within Global Regulatory Affairs.
- Recommend and help implement process improvements.

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

Qualifications (Education & Experience)

- BS degree in a relevant discipline with a minimum of 8 years of bio/pharmaceutical industry experience and minimum 5 years in Regulatory Affairs in the US and EU; advanced degree preferred.
- Proven track record of successfully developing and implementing regulatory strategy for multiple submission types, including large submissions (INDs, NDAs, and MAAs) with intimate knowledge of the electronic Common Technical Document.
- Strong knowledge and understanding of regional (US/EU) and global regulatory science and overall drug development processes and strategies.
- Ability to critically evaluate risks to regulatory activities and develop strategic action plans to mitigate those risks.
- Experience developing and leading interactions with health authorities; experience working with the US FDA Division of Endocrine and Metabolism Products and Division of Gastroenterology and Inborn Errors Products is preferred.
- Recent experience in the cardiovascular or lipid drugs therapeutic areas in the US and Europe is a major plus.
- Excellent verbal and written communication skills; demonstrated success as a regulatory strategy content writer.
- Ability to lead, 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.
- High integrity with respect to maintenance of proprietary, confidential information.
- Strong decision-making and problem-solving skills.
- Ability to work in a dynamic, small-company environment and quickly adapt to changes.
- Ability to handle aggressive timelines and workloads.
- Composure under pressure.

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