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, Global Regulatory Strategy

The Director of Global Regulatory Strategy is responsible for the implementation of the regulatory strategy. The person in this role will ensure that the regulatory strategy will achieve a rapid approval aligned with product and corporate objectives. Available as a remote, work from home opportunity.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Execute the regional and/or global regulatory strategy using knowledge of applicable US, EU and other regional requirements to deliver on milestones designed to achieve a rapid global approvals with advantageous labeling.
- At the Director level, contribute to the development of adaptable strategic regulatory options through regulatory risk planning and mitigation.
- Oversee the management of timely and accurate compilation of all necessary documentation for regulatory submissions, including ensuring the quality, content, and format comply with regional guidelines and regulations.
- At the Director level, support interactions with regional and/or global regulatory agencies (specifically US/EU).
- Represent the Global Regulatory Affairs (GRA) function on clinical trial teams and communicates cross functionally.
- Develop an effective regulatory team by facilitating regular discussions with colleagues focused on objective and timely feedback.
- Coach and mentor internal colleagues on regulatory affairs topics where relevant.
- Other responsibilities as assigned by the supervisor.

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

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Qualifications (Education & Experience)

- BS degree in a relevant discipline with a minimum of 10 years of industry experience 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 (NDA's, IND's, and MAA's) with intimate knowledge of the 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 successfully building, coaching, and managing regulatory teams.
- Excellent written and oral communication skills.
- Cardiovascular experience and/or experience working with the USFDA Division of Endocrine and Metabolism Drugs is preferred.

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