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: Associate Director, Global Regulatory Operations

The Associate Director, Global Regulatory Operations position will manage the content of the regulatory dossier and the overall project plan (Project Management). This position will manage the publishing, RIM, and systems efforts, while interfacing with regulatory operations, project management, and the individual functions responsible for regulatory submission deliverables. This will be a regulatory operations strategic submission management position that will provide leadership to product teams. The person in this position will have a central role in managing the regulatory operations components of submission deliverables and the communication of submission status. Available as a remote, work from home opportunity.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Manage component and submission publishing, and publishing vendors and budget
- Manage RIM activities
- 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.
- Manage submission dossier deliverables in collaboration with regulatory, clinical, preclinical, and CMC functions
- Align content regulatory plan with integrated project plan, tracking dashboard, and leadership team updates.
- Provide key supportive role working with project management and functions to ensure deliverables are on time.
- Work with functions to troubleshoot issues that could affect timely delivery of regulatory deliverables
- Represent global regulatory and project management functions on clinical trial teams and communicates cross- functionally.
- Lead optimization of current systems
- Responsible for timely completion and submission of all regulatory deliverables and filings.
- Manage and mentor staff, and contractors
- Forecast and manage regulatory operations budget
- Other responsibilities as assigned by the supervisor

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

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Qualifications (Education & Experience)

- Bachelor's 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 leading dossier management activities for multiple submission 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 submission deliverables and overall drug development processes and strategies.
- 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.