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, Global Regulatory Submissions

The Senior Manager, Global Regulatory Submissions is responsible for managing the delivery of all regulatory submissions for agency review. Available as a remote position from a home based office.

Preferred Location: Remote - US

Essential Duties and Responsibilities*

- Manages and ensures the timely delivery of submissions (any formal dossier documentation) submitted for agency review.
- Tracks submission timelines and communicates to the team regarding upcoming submissions across the global program.
- Represents the regulatory department in global and cross-functional planning activities as an expert on submissions related processes, systems and standards.
- Contribute to the development of and management of the regulatory submissions timelines and drive the submission processes to completion with subject matter experts across functional teams.
- Responsible to develop submissions operations management and eCTD best practices.
- Oversee the preparation, timelines, submission, distribution and archives of all types of submissions -- globally -- with an understanding of global submission requirements, standards and processes.
- Serve as submissions manager for multiple projects in the USA, EU and other countries, which includes establishing timelines and content plans and collaborating on submission strategy with RA and Project Management.
- Train other staff members and serve as subject matter experts on systems, processes and regulatory requirements.
- Serve as liaison to global regulatory CRO team members to ensure complete CTA packages and associated submissions.
- Troubleshoots any regulatory gaps, conflicts or delays in the regulatory document draft and review process flows.
- Manage the collection of and respond to CRO team members for requests for documentation as it related to regulatory submissions.
- Oversee vendors conducting submission-publishing activities.
- Review and approve forms, correspondence, and study documentation for global regulatory initial submission packages.
- Review and approve global site study start up packages for completeness.

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Essential Duties and Responsibilities Continued*

- Host routine cross-functional meetings related to the planning and progression of submissions specific to clinical, non-clinical and CMC end-goals.
- Work with contract medical writers and subject matter experts to plan and execute writing project specifically related to regulatory submissions i.e. RTQs.
- Serve as back-up Regulatory contact to regulatory agencies as needed.
- Manage a Regulatory Associate supportive role FTE.
- Manage contractors during the preparation and development of upcoming large eCTD applications projects ie NDA.
- Other responsibilities as assigned by the supervisor.

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

Qualifications (Education & Experience)

- Bachelor's degree in scientific discipline; advanced degree preferred.
- Minimum of 4 years of previous industry experience; including in Regulatory Operations and Submissions management or in a role closely associated with interpretation of health authority regulations and/or compilation of submission data in eCTD format.
- Experience in the USA and EU with many submission types.
- Proven expertise in global standards for eCTD and other submission formats.
- High degree of familiarity with FDA CFR, interpreting regulatory guidance and monitoring the external regulatory environment for changes that impact submission standards.

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