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: Sr. Manager/Associate Director, Global Regulatory Affairs CMC

Responsible for managing global CMC regulatory strategies, submissions and compliance activities for all development programs and commercial products. Available as a remote position from a home-based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- The regulatory CMC Senior Manager/Associate Director is responsible for the managing global CMC regulatory strategies, submissions and compliance activities for the development programs (and commercial product, as needed). Supports the preparation of CMC information for submission to global regulatory competent authorities (i.e. FDA, EMA, PMDA), participates in the development of CMC strategies, assesses risks and supports the development of contingency plans.
- Acts as a regulatory representative to support CMC team, or contributes support to the Global CMC representative, within cross-functional project teams. Accountable for assigned projects and activities, independently completing work within assigned work group/project teams, for multiple projects.
- Interprets CMC regulatory requirements, develop strategies (including novel approaches), assess risks and develops contingencies. Uses technical and scientific knowledge to conduct the appropriate analysis of CMC submission documentation. Accountable for assigned CMC programs, managing day-to-day delivery of plans and strategic activities for specific projects, including life cycle management teams and compliance of development and commercial products.
- Creates / contributes to the development of internal relevant policies, processes and procedures supporting the progression and maintenance of the programs at large.
- Serves as a Global CMC strategist for projects, providing regulatory assessments and developing regulatory strategies.
- Responsible for the development and preparation of CMC documentation. May act as a primary writer or coordinator. Responsible for the coordination and management of global submissions (including but not limited to INDs, IMPDs, CTAs, CTNs, DMFs/ASMFs, Health Authority meeting requests and meeting briefing documents).
- Supports the preparation of initial marketing applications for Rest of World (RoW) countries. Coordinates requests and authentication of Certificates of Pharmaceutical Product (CPPs) and compiles ancillary documents (CoAs, GMP Certificates, TSE/BSE Certificates, etc.)
- Supports the regulatory CMC assessment and management of change controls for pre-approval and/or post-approval changes, and for maintaining product compliance.

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Essential Duties and Responsibilities*

- Ability to collaborate effectively across a network of other stakeholders, partners and customers, to deliver high quality CMC submissions and ensuring the compliance of the Esperion pharmaceutical portfolio. Manages the resolution of regulatory CMC/information management issues with project/program stakeholders.
- Able to develop and/or lead projects or team initiatives to support short-term operational goals and contribute to the development of global regulatory initiatives.

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

Qualifications (Education & Experience)

- At minimum a bachelor's degree in Chemistry and/or pharmaceutical sciences is required. A Master's degree is preferred.
- An experienced regulatory CMC professional or an individual with regulatory expertise in pharmaceutical science development or pharmaceutical manufacturing and/or specific regulatory domain (5 - 8 plus years of experience in a relevant field). Ability to interpret and apply global / regional CMC regulatory policies and requirements for assigned projects.
- Candidate is required to have a broad functional knowledge of pharmaceutical sciences / the pharmaceutical industry, with a clear understanding of drug development/commercial manufacturing of pharmaceuticals.
- Technical and scientific understanding of pharmaceutical drug development with technical writing skills. Must have authoring experience for the preparation of Module 2.3 and 3.2 sections for pre-approval and/or post-approval submissions. May serve as Subject Matter Expert in specific relevant disciplines or recognized as a regulatory CMC resource for specific pharmaceutical science projects and/or specialized expert in specific regulatory domains. Experience in providing regulatory assessments of change controls required.
- Competent working knowledge of computer based systems such as Microsoft Office, PowerPoint, electronic document management system. Ability to learn and navigate tracking/change control systems, compliant and consistent use of systems (including GMP validated systems) and willingness to train and support others in system use.

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