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: Head of Regulatory Affairs, CMC

The Head of Regulatory Affairs, CMC will be responsible for leadership and development of global CMC regulatory strategies and oversight of the CMC aspects of global submissions and CMC regulatory activities for all development programs, life cycle management, and commercial products. Available as a remote position from a home-based office.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Keep abreast of current Regulatory Global (e.g. US, EMA, Canada, Japan) Requirements and Guidance. Understand and interpret these CMC regulatory requirements and guidance for impact on Esperion's development programs and products.
- Develops CMC strategies (including novel approaches), assesses risks and develops contingency plans in accordance with corporate goals and timelines.
- Uses technical and scientific knowledge to conduct the appropriate analysis of CMC submission documentation including, but not limited to, briefing documents, INDs, IMPDs, NDAs, MAAs, and sNDAs and leads the preparation of CMC information for submission to global regulatory competent authorities (i.e. FDA, EMA, PMDA).
- Leads the global CMC teams and ensures CMC Regulatory is represented on cross-functional project teams to ensure global CMC regulatory strategy for projects.
- Accountable for overseeing and managing the team responsible for the day-to-day delivery of plans and strategic activities for specific CMC projects, including CMC aspects of global submissions and CMC regulatory activities for all development programs, life cycle management, and commercial products.
- Leads the development of internal regulatory CMC policies, processes and procedures supporting the progression and maintenance of all programs.
- Provides leadership to the CMC regulatory staff by serving as a mentor and providing advice and direction.
- Ensures open communication channels among and within cross-functional project teams and with technical CMC teams.

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

- continued on page 2 -

Qualifications (Education & Experience)

- Bachelor's degree in Chemistry and/or Pharmaceutical Sciences required. Master's or Ph.D. degree preferred.
- Minimum of 15 years of regulatory CMC experience within the Pharmaceutical Industry with specific emphasis on pharmaceutical development and/or biopharmaceutical manufacturing.
- Background in small molecule regulatory development is required with tablet experience preferred.
- Experience with 505b2 applications a plus.
- Ability to understand, interpret, and apply global /regional CMC regulatory policies and requirements to assigned projects.
- Broad functional knowledge of the Biopharmaceutical industry including knowledge of pharmaceutical sciences with a clear understanding of drug development/commercial manufacturing of biopharmaceuticals.
- Technical and scientific understanding of biopharmaceutical drug development with technical writing skills.
- 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.
- Competent working knowledge of computer based systems such as Microsoft Office, PowerPoint, electronic document management system, etc.
- 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.

Notice to Agency and Search Firm Representatives: *Esperion Therapeutics is not accepting unsolicited assistance from agencies and/or search firms for any job posted on this or a referring site. Please, no phone calls or emails. All resumes submitted by an agency and/or search firm to any employee at Esperion via email, the internet, or in any other form and/or method without a valid written agreement in place will be deemed the sole property of Esperion. No fees will be paid in the event that a candidate is hired by Esperion as a result of an unsolicited agency and/or search firm referral.*

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