

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: Manager, Pharmacovigilance

The Manager, Pharmacovigilance will be responsible for reviewing serious adverse events, overseeing the reconciliation and coding processes, and providing subject matter expertise on background safety information for reports and documents. Available as a remote position from a home-based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- Performs reviews on serious adverse events including query identification and quality control to ensure accurate and comprehensive safety reports are created
- Serve as back-up for Drug Safety Specialist in data entry/narrative creation of SAE reports
- Ensures that internal and external regulatory reporting timelines are met
- Performs or oversees SAE reconciliation and coding review processes
- Provides background safety information in support of developing and updating reports and documents (investigator brochures, protocols, annual reports, etc.)
- Responsible for leading, managing and mentoring direct reports, as applicable
- Interactions at various management levels across cross-functional teams
- Contacting clinical trial site personnel to obtain missing or necessary information for SAE reports
- Collaborates with other departments to ensure appropriate collection and handling of safety data
- Other PV activities appropriate to experience and expertise

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

Qualifications (Education & Experience)

- BS degree in science with 5-7 years of experience in drug safety/pharmacovigilance; or equivalent education and experience
- Experience supporting regulatory submissions
- In-depth understanding of best drug safety practices
- Safety database proficiency (ARISg, ARGUS)
- Knowledge of domestic and international drug safety regulations
- Strong scientific clinical base knowledge
- Previous experience working with study protocols, case report forms, investigator brochures and participation on IND annual reports
- Understanding of the drug development process
- Thorough knowledge of US and ICH safety reporting regulations and guidelines.
- Excellent verbal and written communication skills including excellent telephone etiquette.
- Should be comfortable in speaking with clinical site/study personnel.
- Committed, self-motivated team player.
- Strong problem solving skills.
- Ability to meet the demands of a position in a dynamic organization.
- Ability to operate independently by planning, scheduling and arranging activities in accomplishing objectives.
- Ability to meet internally and externally required deadlines.
- Strong organizational abilities and strong attention to detail.

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.