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: GCP Compliance Manager

Responsible for GCP compliance for all clinical studies including conducting audits of vendors and clinical sites. National and international travel as needed. Available as a remote position from a home-based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- Ensures GCP compliance for all clinical studies (Phases I-IV).
- Conduct qualification audits of vendors supporting Esperion clinical development activities to provide assurance that these activities worldwide are conducted in compliance with Good Clinical Practice (GCP) regulations, and the International Conference on Harmonization (ICH).
- Participate in oversight of vendors completing clinical functions.
- Perform audits of clinical investigator sites. Ensure complete and adequate follow-up is completed.
- Participate as a QA member of project team for clinical studies.
- Assist Director in oversight of vendors and consultants conducting clinical investigator site audits.
- Maintain a current working knowledge of the US and EU GCP requirements, ICH Guidelines, industry practices, internal policies and procedures that impact regulatory compliance.
- Participate in the development and implementation, of standard operating procedures for Clinical Quality Assurance activities. Provide training as required.
- National and international travel as needed.
- 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 life-science and with a minimum of 6+ years of relevant experience in quality assurance required.
- Experience in pharmaceutical development with a good understanding of the drug development process.
- Technical and scientific knowledge to manage quality assurance oversight for clinical supply activities preferred.
- Expert knowledgeable in US and EU ICH/GCP, SOPs and local regulatory requirements.
- Effective oral and written communication skills.
- Team-oriented, collaborative style, with an ability to build consensus among both internal and external constituents.

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