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: GMP Compliance Manager

Responsible to serve as the cGMP subject matter expert providing guidance on conformance with cGMP and Esperion quality standards for drug supply. Available as a remote position from a home-based office.

Preferred Location: Remote

Essential Duties and Responsibilities*

- Provide Quality oversight of drug supply operations and data review for accuracy, completeness, and conformance to current Good Manufacturing Practices (cGMP) and Esperion quality standards.
- Provide guidance to Esperion on all cGMP-related issues. Serve as the company cGMP subject matter expert.
- Ensure Esperion investigational medicinal products (IMP) are packaged and distributed to the study sites in compliance with cGMP regulations and the International Conference on Harmonization (ICH).
- Monitor and audit vendors labeling, packaging, and shipping for cGMP compliance. Ensure audit responses/corrective actions are completed are completed in a timely manner and adequately documented.
- Analyze and report quality trends to the appropriate functional areas and company management.
- Interact closely with clinical supply groups and other development team members as necessary. Participate in development team meetings.
- Review and approve all associated clinical supply batch records and issue batch release.
- Provide appropriate risk analysis for key stakeholders to make critical decisions.
- Maintain a current working knowledge of the US and EU GMP requirements, ICH Guidelines, industry practices, internal policies and SOPs that impact regulatory compliance for clinical supply activities.
- National and international travel as needed.
- Other responsibilities as assigned by the supervisor.

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

-continued on page 2-

Qualifications (Education & Experience)

- BS/MS degree in an area of life-science with a minimum of 5 years of experience performing a quality assurance function.
- Possesses the necessary technical and scientific knowledge to manage quality assurance oversight for clinical supply activities.
- Experience in pharmaceutical development with a good understanding of the drug development process.
- Expert knowledge of cGMP, ICH, USP and FDA quality guidelines and regulations.
- Effective oral and written communication skills.

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