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: Associate/Director of GMP Quality Systems (DP)

Preferred Location: Remote

Essential Duties and Responsibilities*

- Provide quality support in Drug Product GMP operational areas, including change control, deviations/investigations, root cause analysis, corrective actions and preventive actions (CAPAs), complaints, and training.
- Conduct quality reviews of Drug Product Investigational Product and Commercial quality records and reports, including but not limited to batch records, quality control specifications, analytical method validation protocols and reports, stability protocols and reports.
- Establish and maintain quality oversight of Drug Product vendors (manufacturing, packaging and labelling) including performing vendor qualifications (by paper and/or physical audits), establishing/monitoring compliance to Quality Agreements, and utilizing quality metrics to track vendor performance.
- Provide quality oversight to the Drug Product requirements for investigational product CMC submissions (INDs), and for Annual Product Reviews
- Contribute to the implementation and maintenance of the Esperion quality management system. Ensure that all required quality systems procedures related to cGMP drug product manufacturing are established, and are periodically reviewed, to maintain the highest standards of safety, efficacy and quality for Esperion Drug Products (Commercial and Developmental (preclinical; clinical Phase I-Phase III)).
- Organize and promote companywide quality systems continual improvement programs. Evaluate and develop improved systems and processes for the control of quality, reliability and safety.
- Assist in the preparation and management of regulatory agency inspections.
- Standard Operating Procedure (SOP) administration
- Assist in the development and administration of the Personnel Training Program
- Oversee Quality Assurance Drug Product GMP Batch Record Review and Release
- Review and approve Drug Product quality investigations and associated CAPA
- Review and approve Drug Product complaint investigations and associated CAPA
- Review and approve Drug Product change control

- Review and approval of Drug Product validation protocols
- Assist in the development of Drug Product quality agreements with key vendors
- Assist in the performance of Drug Product vendor assessments

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

Qualifications (Education & Experience)

- Must have a minimum of a Bachelor's degree in life sciences with a preference for a Master degree.
- Must have a minimum of 5 years of related work experience in Quality Assurance/Quality Management within the pharmaceutical or biotechnology industry doing drug development and commercial supply.
- Must have a working knowledge of FDA, EU, and ICH Regulatory requirements and guidelines specific to the areas of Drug Product quality.
- Must have demonstrated working knowledge of Drug Product cGMP quality system requirements for solid oral dosage forms.
- Intermediate to advanced experience with MS Office software required, MS Project preferred.

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