

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 Quality Assurance

The Head of Quality Assurance will oversee the development of Esperion’s global GxP quality strategy, ensure compliance to the strategy through training and quality metrics reviews, and direct the functional resources needed to execute this strategy. This position is available as a remote, work from home opportunity.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Oversee the development of a Quality Management System in full compliance with all regulatory requirements.
- Ensure the internal/external audit and compliance strategies are executed in a manner to meet full compliance with all regulatory requirements.
- Review Quality metrics to monitor performance and provide recommendations to senior management.
- Oversee all GxP Quality-related aspects for organizations providing contracted services.
- Oversee development of budgets for accountable departments and ensure expenditures are within budget.
- Manage personnel in all accountable departments with a focus on retention and development.
- Review and approve compliance documentation including approving regulatory filings for products.
- Develop a culture of quality across the company.
- Act as Quality interface with current and potential corporate partners.
- Monitor industry trends and regulatory expectations to ensure evolution of the Quality Management System and compliance strategy.
- Ensure a corporate training program is in place so all employees are compliant with the relevant SOPs and internal guidelines.
- Establish and maintain a positive working relationship as a thought leader with FDA and other regulatory authorities. Represent the Company both internally and externally on any Quality and GxP compliance issues.

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

Qualifications (Education & Experience)

- Bachelor's degree in Quality Management or related science discipline required; Advanced degree (MS, PhD, MBA) preferred.
- 20+ years of experience working in the Pharmaceutical/Biopharmaceutical industry with at least 5 years in a leadership role managing quality systems/organization for branded commercial pharmaceutical products is required.
- Experience in multiple disciplines within Quality (e.g. auditing, GCP and GMP oversight, electronic systems management, laboratory management, PAI inspection readiness, commercialization and leadership)
- Must have in-depth knowledge of FDA and EU guidelines and have a proven track record in implementing these guidelines in fast growing environments.
- Established experience in dealing with high-level regulatory authorities such as the FDA and other international regulatory authorities.
- Demonstrated leadership successes in building and creating functions and infrastructure.
- Strong ability to analyze complex issues to develop relevant and realistic plans, programs and recommendations.
- Demonstrated success in leading pre-approval inspections by FDA and other regulatory agencies.
- Possess strong conflict management and negotiation skills.
- Excellent verbal and written communication skills
- Self-motivated, able to work independently and be reliable and responsive

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.