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: VP, Manufacturing

The VP, Manufacturing is responsible for overseeing the global manufacturing for Esperion's bempedoic acid franchise. This role will oversee the execution of the organization's contract manufacturing relationships and the flow of Esperion's products through production, including the planning of production schedules, coordinating materials requirements, and formulating and recommending manufacturing policies and programs. This position is available as a remote, work from home opportunity.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Develop a drug substance and drug product CMO partnership strategy to support a growing portfolio of late stage clinical assets into commercial product and launch.
- Develop and implement an effective manufacturing plan with our CMO partners to achieve company goals for product quality, on-time delivery, effective inventory management, and manufacturing efficiencies and productivity.
    - Ensure facility is maintained in a constant state of inspection readiness ensuring that all staff are compliant with cGMP and all related elements such as facilities, documentation (SOPs and validation protocols etc.), training, reports, and records.
    - Ensure safety throughout operations and identify preventative plans to prevent accidents
    - Ensuring that all equipment, as proscribed through regulation is available and in good working order
    - Initiate recommendations on purchasing of new equipment and improvements
- Direct the team to oversee availability of raw materials, drug substance and drug product manufacturing, packaging and inventory management, supply chain management and delivery processes
- Establish quantitative metrics consistent with the company's business objectives for leadership in product cost, quality and delivery.
- Accountable for product cost drivers, overall cost of ownership, risk management, compliance and ongoing cost improvement for all products.
- Ensure fulfillment of agreed Manufacturing service for clinical and commercial supply
- Drive and establish the drug substance and drug product specification setting process
- Provide management with routine updates regarding the productivity and efficiency of operations
- 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.
- Act as Manufacturing interface with current and potential corporate partners.

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Qualifications (Education & Experience)

- Bachelor's degree in a related pharmaceutical science/engineering 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 large scale commercial manufacturing of small molecule product is required.
- Experience in multiple disciplines within Manufacturing.
- Must possess a broad knowledge of oral solid dosage pharmaceutical manufacturing.
- Must have in-depth knowledge of GMP compliance and quality 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 participating in 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

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