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: Director, Packaging Technology

The Director, Packaging Technology will lead and manage the packaging design, development, and ongoing packaging technology support for commercial products. He/she is responsible for the design, coordination, development and implementation of commercial packaging systems in support of the pharmaceutical businesses. Recognized as a technical expert for packaging design, materials, processes, and problem resolution, the role will interface with other functions such as: Marketing, Regulatory Affairs, Quality Assurance, Supply Chain and Commercial Operations. Performs other tasks and projects in Strategic Operations as assigned. The Director, Packaging Technology reports to the VP of Strategic Operations. This position is available as a remote, work from home opportunity.

Preferred Location: Remote – US; NJ Preferred

Essential Duties and Responsibilities*

- Designs, evaluates, and implements above best class packaging and associated processes for pharmaceuticals through competitive benchmarking and customer feedback.
- Direct the change management activities including:
    - New Product launches or product extensions
    - Manages the approval and implementation of new and changed product components
    - Measures, analyze, and report key process metrics.
    - Troubleshoots and problem solves as necessary.
- Represents Strategic Operations in project team meetings and works closely with Marketing, Commercial Operations groups, Regulatory Affairs, Project Management, Supply Chain, and Quality Control to meet project timelines and objectives.
- Develops and maintains a current in-depth knowledge of global regulatory submission requirements, GLP/GMP requirements & (ISO 9000 where required), and maintains up to date knowledge of state of the art solutions and device packaging strategies though trade journals, seminars, and trade shows.
- Vendor Management – working with key stakeholders (e.g. Quality, Procurement, Finance) develop an appropriate program for Vendor Management of all activities.

Essential Duties and Responsibilities Continued

- Packaging initiatives:
    - Identify and implement supply chain opportunities to realize improvement in service and cost
    - Develop and present business cases for stakeholder approval
    - Effectively communicate and present the progress of initiatives and programs to stakeholders
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- 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
- Accountable for packaging cost drivers, overall cost of ownership, risk management, compliance and ongoing cost improvement for all products.
- Drive and establish the packaging specification setting process.
- Oversee development of budgets for accountable departments and ensure expenditures are within budget.
- Act as packaging technology interface with current and potential corporate partners.

Qualifications (Education & Experience)

- B.S. in Business, Pharmacy, Engineering or Life Sciences. A major or focus on packaging engineering is preferred.
- 15 years' pharmaceutical industry experience in Packaging Engineering and technology related activities
- Experienced in supervising small teams or leading Project teams
- Proven leadership in developing new business processes and moving them to automated systems and implementation
- Ability to work/lead in a dynamic group that takes a multi-disciplined team approach to executing and achieving departmental and corporate goals
- Excellent interpersonal and communication skills
- Superior communication skills (both written and oral) are essential. Experience working in a multi-cultural, multi-lingual environment is necessary with a demonstrated ability to contribute successfully in a multi-disciplinary team environment.
- Must have hands on experience in managing diverse project activities with pharmaceutical drug product manufacturing facilities at different geographical locations.
- Strong project management experience with cross-functional team leadership and participation skills.
- Demonstrated ability to successfully work with and influence contract manufacturing partners while maintaining a positive working relationship.
- Requires expert understandings of packaging, technology transfer; cGMPs, FDA, EU, ICH guidelines; as well as CMC content of regulatory submissions.
- 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

Qualifications (Education & Experience) Continued

- Specialized knowledge, Licenses, etc.:
  - Demonstrated experience in the launch of new products in a commercial setting. Strong understanding and working knowledge of cGMPs for pharmaceutical development and commercial operations.
- Working conditions (ability to travel, lifting, etc.):
  - Office environment with extensive international travel required (20 to 30%)

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.