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: Manager, Chemistry and Manufacturing

The Manager, Chemistry and Manufacturing is responsible for supporting the company's efforts in outsourcing the manufacture of active pharmaceutical ingredients (API) for Esperion's lead drug products in various stages of clinical development and in preparation for scale up to commercial manufacturing.

Preferred Location: Ann Arbor, MI

Essential Duties and Responsibilities*

- Assist in the management of activities at various CMO's engaged in cGMP manufacture of API for Esperion
- Interact with cross-functional teams in project management, analytical chemistry, QA and regulatory affairs to move projects forward and adhere to project timelines
- Review manufacturing batch records and advise on document management under cGMP guidelines
- Advise and participate in activities related to quality systems for mitigation of OOS, CAPA and other quality related activities
- Manage documentation for process validation and commercial manufacturing in preparation for regulatory filings (NDA, MAA and related supplementary filings)
- Manage source documentation for cGMP manufacturing campaigns (raw materials, IPC/release testing) for regulatory filings
- Participate in planning sessions and cross-functional team meetings

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

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Qualifications (Education & Experience)

- BS in Chemistry; MS in chemistry desired
- 4-7 years' experience in cGMP manufacturing environment (pharmaceutical industry)
- Solid background in multi-step small molecule drug substance manufacturing processes
- Extensive training in cGMP guidelines
- Familiarity with batch record review process and FDA quality standards
- Experience with quality systems in a regulated environment – working knowledge and experience with SOPs and ICH guidelines
- Some experience managing CMO's desired (but not essential)
- Proficient with MS Word and Excel

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