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/Director, Pharmaceutical Science

The Associate Director/Director, Pharmaceutical Science is responsible for the design and development of formulations and processes according to QbD, scale up and manufacturing of clinical batches, and preparation of technical documents for regulatory submissions. Available as a remote position from a home-based office.

Preferred Location: Remote - US

Essential Duties and Responsibilities*

- Management of activities for development and manufacturing of drug product at CMOs. This includes but not limited to: development of new solid oral formulations, process development and optimization, review and approval of drug product manufacturing batch records, and supervision of other manufacturing activities at CMOs as required.
- Prepare gap analysis for drug product NDA package, and identify areas of deficiency and needs for additional studies.
- Prepare technical drug product documents for regulatory submissions and intellectual property.
- Interface with project management, project team, and finance for timely execution of the plans.
- Interface with consultants to optimize formulation development and manufacturing process.
- Interface with legal, QA and regulatory consultants for ensuring compliance in the manufacturing of drug product under current GMP standards.
- Prepare product development updates and presentations as required.
- All other projects and responsibilities as assigned by the management and supervisor.

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

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Qualifications (Education & Experience)

- Ph.D./M.S. in pharmaceutics, pharmaceutical science, pharmaceutical technology or other related sciences
- 8+ years of experience in pharmaceutical drug product development from early development to commercialization.
- Proficient in development of solid oral dosage forms. Experience with oral combination products is a plus.
- Demonstrated experience with preparation of technical drug product documents for regulatory submissions.
- Excellent knowledge of QBD, GMP, and ICH and FDA guidance for drug product.
- Proven track record of successfully managing CMOs.

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