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: Global Regulatory Affairs, Document Specialist (RDS)

The Global Regulatory Affairs, Document Specialist (RDS) will report to the Associate Director, Regulatory Affairs and will be responsible for ensuring that all documents for regulatory submissions and presentations meet the quality standards set forth by the company in the Esperion Style Guide and applicable standard operating procedures (SOPs). The RDS will conduct document formatting and quality check activities across functions for the purposes of preparing documents for global regulatory submissions.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- The role will insure the formatting, quality, and completeness of key regulatory submission documents that include but are not limited to:
  - Regulatory Dossier Documents
  - Clinical Protocols and Clinical Study Reports
  - Nonclinical Protocols and Reports
  - Reviewer's Guides, Tables, Figures and Listings
  - BIMO, Financial Disclosures and Adjudication Packages
  - Presentation and Slide Decks
- The candidate will have keen attention to detail and the ability to identify and (when appropriate) correct grammatical errors, erroneous data points that have been cross checked against source documents and inconsistencies in style and formatting.
- The candidate will be expected to establish clear processes for receiving document project requests from team members across functions. The candidate will work within or establish a timeline for completion of each project, and be expected to self-govern and lead projects to completion.
- The candidate will be expected to work with cross-functional team members to adequately report findings and manage resolutions.
- The candidate will own the process for updating the Esperion Style Guide and will be accountable for developing SOPs and tools for formatting and performing quality check of documents.

Essential Duties and Responsibilities Continued*

- Assists in the development and implementation of documentation standards by establishing templates, guides, checklists, process and procedures, including SOPs and work practices, related to the formatting and quality checks including routinely updating the company style guide.
- Manage the process for receipt of document formatting and quality requests and training the team members to ensure the process is followed and traceable.
- Perform quality checks and formatting for key documentation within GRA and from other functions to support outgoing submissions.

Qualifications (Education & Experience)

- Bachelor's degree
- Three to five years pharmaceutical regulatory experience or equivalent
- Excellent writing, editing, formatting verbal, and communication skills
- Knowledge of eCTD
- Experience with StartingPoint Templates or equivalent
- Strong proficiency in MS Office, MS Excel and MS Power Point
- Experience with an Electronic Management System preferred

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