Associate Director/Director, Regulatory Affairs CMC
Job Description

Position Summary

Reporting to the Vice President of Regulatory Affairs and Quality Assurance, the successful candidate will lead the CMC regulatory function and collaborate cross-functionally to develop the CMC regulatory strategy, provide guidance to the CMC subject matter experts, and drive the CMC regulatory submissions to facilitate the global development of serlopitant, a small molecule.

Key Responsibilities

- Lead preparation, coordination, review, and maintenance of CMC content in regulatory submissions (e.g., INDs and CTAs, annual reports, Briefing Documents, NDA/MAA), to ensure timelines and corporate goals are met
- Represent regulatory function in CMC subteam, and develop CMC regulatory strategies
- Provide regulatory CMC advice and direction, including the interpretation and application of global CMC regulations and guidance
- Manage technical assessments of CMC source documentation and responses to technical questions on document content
- Proactively identify potential CMC program risks and implement appropriate regulatory mitigation strategies to support successful NDA/MAA submissions
- Oversee and ensure compliance with quality assurance and regulatory procedures and work practice
- Initiate and/or contribute to local process improvements which have an impact on Regulatory Affairs or other departments. Develop and implement regulatory operating guidelines/SOPs for regulatory CMC activities and common work practices/strategies within the team
- Involvement in preparation for and management of CMC interactions with Health Authorities
- Train, mentor and supervise, as needed, regulatory employees, consultants/contractors in Regulatory Affairs. Maintain a positive team spirit and lead by ethical principles

Qualifications and Requirements

- Ph.D, Master's degree (or equivalent), or Bachelor's Degree at a minimum, in life sciences or chemistry
- 10+ years of experience in Regulatory Affairs or related function within a biotechnology company
- Established working knowledge of regulatory guidelines and regulations (US and international)
- Direct experience leading regulatory CMC aspects of investigational small molecule essential, global experience (US and EU) preferred
- Successful submissions to FDA and demonstrated evidence of writing of CMC aspects of regulatory documents
- Strong eCTD knowledge and regulatory writing skills
- Detail oriented with excellent oral and written communication skills, including proficiency in scientific writing, and experience interfacing with all levels of management, CMC/cGMP Quality Assurance consultants, and contract manufacturing organizations (CMOs)
- Strong organizational skills and ability to maintain a high level of communication, productivity, innovation, and priority-setting to work effectively in a dynamic environment to meet aggressive timelines

- Strong knowledge of cGMP for small molecule, and CMC Regulatory Affairs
- Self-motivated, self-disciplined, and able to function independently as well as part of a team
- Strategic agility, strong critical and logical thinking with ability to analyze and propose solutions to problems
- Excellent computer proficiency (MS Word, Excel, PowerPoint, Visio, Adobe Acrobat)

Benefits Offered

Menlo offers a competitive benefits package that includes the following:

- A compensation structure that includes a competitive base salary, a stock option grant in a company with successful phase 2 clinical data and an annual cash bonus that aligns with corporate objectives.
- A broad range of medical, dental, and vision plans offered through Trinet, with generous company reimbursement of a significant portion of premiums
- A 401k plan and Flexible Spending Accounts for both dependent care and healthcare expenses
- No set limits on personal time off with manager approval
- Career development support, including manager-approved training and conference attendance throughout the year
- A flexible work schedule that includes 1-2 days' work from home per week
- Lunch provided on in-office days
- Paid Maternity leave up to 12 weeks

About Menlo Therapeutics

We are a late stage biopharmaceutical company focused on the development and commercialization of serlopitant for the treatment of pruritus, or itch, associated with dermatologic conditions such as psoriasis and prurigo nodularis. We are concurrently evaluating the use of serlopitant for the treatment of refractory chronic cough, a cough that persists for greater than eight weeks despite treatment of any identified underlying cause. We believe that serlopitant, a highly selective small molecule inhibitor of the neurokinin 1 receptor, or NK_1R, given as a once daily, oral tablet, has the potential to significantly alleviate pruritus and refractory chronic cough symptoms.

At Menlo, we have a diverse team of highly motivated individuals with strong experience in drug development. We expect a lot out of our employees, and in turn our employees are allowed tremendous autonomy and flexibility in achieving their goals.

All individuals, regardless of race, color, religion, age, gender, gender orientation, national origin, and disability or Veteran status are encouraged to apply.

Visit our website at www.menlotherapeutics.com to learn more about Menlo.