Director, Quality Assurance

Job Description

Position Summary

Reporting to the Vice President of Regulatory Affairs and Quality Assurance, the Director, Quality Assurance will provide compliance leadership and work with quality management, external auditors, in conjunction with clinical department to ensure GCP and GLP compliance across all Menlo projects. Additionally, the position will be responsible for implementing clinical compliance plans to include external GCP audits of clinical services providers, CROs, suppliers, and investigator sites, as well as internal audit of clinical processes and procedures.

Key Responsibilities

- Formulate GCP compliance strategy and provide advice for all programs within Menlo
- Assess GCP and GLP compliance risk areas and develop and implement risk mitigation measures
- Develop and prioritize an audit strategy for all programs
- Plan and lead GCP and GLP compliance audits (US and international), including clinical investigator sites, contract clinical laboratories and CROs to determine compliance status and identify compliance risks
- Report audit findings to management with recommendations for resolution and verify appropriate corrective actions have been implemented and documented
- Partner with Clinical Development, Clinical Operations, Nonclinical and Regulatory Affairs stakeholders regarding compliance issues and provide compliance guidance to audited parties to encourage process improvement, serve as an expert in the interpretation of GCP and GLP regulatory requirements and expectations
- Manage QA reviews of project-related of essential clinical study documents
- Manage regulatory authority inspections and the coordination of responses to resolve inspection findings, if any
- Lead GCP/GLP training of functional areas and develop appropriate training for personnel involved in the execution of clinical trials and nonclinical studies
- Develop and implement standards, policies, and procedures for GCL/GLP regulatory compliance
- Report and escalate compliance issues to management, including requests for directed audits
- Participate in quality and compliance improvement initiatives within and outside of Clinical Development/Clinical Operations departments
- Participate in the evaluation and selection of CROs and other clinical and nonclinical service providers
- Provide guidance, interpretation and information on GCP and GLP regulations, standards and quality systems
- Prepare internal QA reports, and provide input for external partners reports and/or regulatory filings.

Qualifications and Requirements

- BS/BA degree in scientific discipline from an accredited college or university or equivalent experience. Advanced degree preferred

- 8 to 10 years of relevant pharmaceutical industry experience, with a minimum of 5 years of GCP compliance, preferably in an FDA regulated environment. Experience in large pharmaceutical industry and start up environment preferred
- In-depth knowledge of and ability to interpret and apply GCL, GLP, EU, FDA and ICH regulations, guidelines, and best practices
- Experience in planning and conducting GCP and GLP audits
- Experience with regulatory inspections and inspection readiness (EU experience is a plus)
- Experience with Quality Management Systems (e.g., documentation and record management, change control, deviations, investigations, training and CAPA programs)
- Experience reviewing and auditing study-related documentation (e.g, nonclinical and clinical study reports, Investigator's Brochures)
- Strong team player with demonstrated track record of success in a cross-functional team and fast moving environment
- Excellent organizational, computing and oral/written communication skills
- Ability to influence and negotiate effective solutions
- Strong critical thinking and decision making skills
- Ability to travel up to 30%

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 atopic dermatitis, 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.