



## **GCP Auditor**

**Omeros Corporation is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation and disorders of the central nervous system.**

This position performs a wide variety of activities to ensure compliance with applicable regulatory requirements.

### **Essential Duties and Responsibilities**

- Provide audit support with emphasis on auditing the clinical trials to assure adherence to company Standard Operating Procedures, and any applicable regulatory requirements.
- Review audit responses for acceptability; elevate issues that are above incumbents abilities or that cannot be resolved.
- Recommend corrective and preventive actions to compliance issues and/or observations as needed.
- Monitor corrective action process to ensure that corrective actions are being implemented.
- Maintain databases for investigations, audit observations, and CAPAs.
- Keep informed of current worldwide regulatory requirements.
- Share responsibility with team for the development of training materials and conduct training as needed.
- Write and review Standard Operating Procedures as needed.
- Assist with preparation of, coordination, and management of regulatory agency inspections
- Provide support for document management.

### **Qualifications**

- University degree in science and 5 years of experience in Quality Assurance or clinical research.
- At least 2 years Good Clinical Practices auditing experience
- In-depth knowledge and experience with GCP regulations, and industry standards.
- Expert organizational, written and verbal communication skills with the ability to present in a professional manner are required.
- Knowledge of the principles and practices of computer applications including word processing, spreadsheet, database management, and presentation software and internet search engines.
- Must have the ability to build and maintain positive relationships with management, peers, and subordinates.
- Must display strong analytical and problem solving skills with attention to detail.
- Self-motivated and able to function effectively within team.

**Omeros Corporation**  
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**Reference Position OMS-C40-171**

**Omeros is an Equal Opportunity Employer.  
Send cover letter and resume to [hr@omeros.com](mailto:hr@omeros.com).**