Senior Director, Quality

Remote

Summary

Reporting to the Vice President, Global Regulatory Affairs and Quality, the Senior Director, Quality will focus on leading the company in developing and updating an appropriate Quality Management System to support GXP operations.

Responsibilities

- Implement appropriate quality management systems and supporting Standard Operating Procedures (SOPs) to ensure GxP compliance across all aspects of the clinical drug supply chain and the conduct of non-clinical and clinical studies in support of drug development and approval.
- Provide ongoing GLP, GCP and GMP training as needed, and act as a quality resource to ensure regulatory compliance.
- Oversee the review and approval of investigations of violations affecting Development and Operations activities, approving corrective action recommendations and final conclusions.
- Develop and implement quality management strategy and plans, including resource, systems, timescales, financials, to support, contribute to, and integrate with, the organization's annual business plan and long-term strategy.
- Develop and maintain systems to establish standards relating to activities and products.
- Develop and maintain systems to measure performance against established standards.
- Internal and External GLP, GCP and GMP Audit Scheduling, Planning and Execution.
- Work closely with Project Teams to ensure adherence to protocols, SOP's and regulations/guidelines.
- Experience/background with document management and document control practices.
- Occasional international travel to attend meetings as required.
- Other related duties as assigned.

Qualifications and Requirements

- Bachelor of Arts/Bachelor of Science in a related discipline and 8-10 years of experience in quality assurance or compliance supporting GCP, GMP, GLP operations in a pharmaceutical company, or the equivalent combination of education and experience.
- Previous supervisor/management experience is strongly preferred.
- Experience with FDA/HA inspection readiness and successful inspections, conducting QA audits, and working with pharmaceutical processes are necessary.
- Previous experience conducting compliance auditing of clinical sites, CRO's, laboratories and or vendors for a Pharmaceutical manufacturer, and detailed knowledge of regulated documentation systems is highly desirable.
- A strong working knowledge of cGMP, GCP, GLP, GDP, ICH guidelines, general compliance regulations and their application is necessary.
- Must be able to travel without any legal restrictions across international borders.

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.