CoNCERT Pharmaceuticals Inc.

Title: Manager, QA Documentation and Training

Job Summary:

Reporting to the Sr. Director, Quality Assurance, the Manager, QA Documentation and Training is responsible for managing the QA Document Control System and GxP Training Program, ensuring compliance to quality objectives and applicable cGMP, GLP, and GCP regulations. The Manager will work with cross functional teams to maintain the internal quality systems associated with GxP activities.

Responsibilities:

- Build-out, management and continuous improvement of the Documentation and Training systems
- Facilitates the Training Program
    - Assist in the development and ongoing maintenance of the GxP Training Program
    - Assessing training needs and priorities.
    - Establishes and maintains training curriculum
    - Develops and conducts GxP Training
    - Perform training needs assessment and recommend training programs, curricula and training material development
- Manage Document Control and Archive
    - Evaluate and report on document control and training metrics, as well as effectiveness of programs
    - Manage the document review process
    - Manage Document/Record Archive Program
    - Oversee the management of incoming external documentation from CROs and CMOs as required
    - Manages documentation during regulatory inspections
- Additional responsibilities
    - Support validation of electronic document and training systems
    - Will act as System Administrator upon implementation of electronic document management system
    - Perform internal audits as required
    - Trend and report QA related metrics both internally and from external activities
    - Facilitate the execution of QA systems to support GxP from both an internal and external perspective
    - Assist with other GxP programs and reviews as needed, driving closure of quality systems
    - Write, review and approve Standard Operating Procedures (SOP) and Forms for the organization

Qualifications:

- Minimum of 5+ years' experience in GxP regulated industries
- 3-5 years of experience with EDMS and/or a LMS
- Extensive knowledge and experience in GXP and QA principles, practices & industry standards
- Experience using risk-based principles & decision making to ensure compliance at all stages of development
- Excellent attention to detail, project and time management skills, and the ability to manage multiple priorities with aggressive timelines
- Excellent written and verbal communication skills
- Ability to work effectively/congenially both independently and with a multi-disciplinary team
- Experience performing internal audits
- Experience with Computer System Validation
- Proficient in Microsoft Word, including document formatting, application of styles and numbering, tracked changes and comments.
- Proficient in Excel, PowerPoint and Adobe Acrobat
- Experience working in small pharmaceutical company is preferred

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If you would like to be considered for a job on the Concert team, send your resume to: careers@concertpharma.com.

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