CoNCERT Pharmaceuticals Inc.

Title: Associate Director/Director, Quality Assurance

Job Summary:

Reporting to the Sr. Director, Quality Assurance, the Associate Director, Quality Assurance is responsible for the execution and administration of GXP Quality Systems as they pertain to applicable cGMP, GLP, and GCP regulations. The Associate Director will work with cross functional teams to maintain the internal quality systems associated with GxP activities as well as interfacing with CMO/CROs.

Responsibilities:

- Perform Quality & Compliance oversight for manufacturing, nonclinical, clinical, & supply chain activities
- Assist in build-out, management and continuous improvement of the QMS and SOP system
- Assure consistency in achieving product quality and compliance across multiple CMOs and CROs
- Assist in the execution of QA systems to support GxP from both an internal and external perspective
- Review batch records and associated documentation, i.e., deviations, OOSs, investigations, specifications, etc.; lead internal investigations.
- Trend and report QA related information (deviations, investigations, CAPA) both internally and from external activities
- Plan audit calendar, perform internal/external audits
- Provide "man-in-plant" observation/feedback at key manufacturing milestone activities
- Review and negotiate Quality Agreements; review MSA/SOW to ensure compliance with the QA agreement
- Assist and/or conduct training
- Write, review and approve Standard Operating Procedures (SOP) and Forms for the organization
- Assist with other GXP programs and reviews as needed

Qualifications:

- BA/BS in Life Sciences
- Minimum of 10 years' experience in GxP regulated industries
- 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
- Experience auditing contract organizations, auditor certification preferable
- Experience working in small biopharmaceutical company and/or experience working within a virtual manufacturing company utilizing a number of contract manufacturing organizations is preferred
- Excellent attention to detail, project and time management skills, and the ability to manage multiple priorities with aggressive timelines
- Ability to travel up to 25% of the time
- Excellent written and verbal communication skills
- Ability to work effectively/congenially both independently and with a multi-disciplinary team

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If you would like to be considered for a job on the Concert team, send your resume in the body text of an e-mail (no attachments please) to: careers@concertpharma.com.

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