

Title: Associate Director, Quality Assurance

Job Summary:

Reporting to the Sr. Director, Quality Assurance, the Associate Director, Quality Assurance is responsible for assisting with compliance oversight of Concert's vendors and execution and administration of Concert's internal GxP Quality Systems as they pertain to applicable cGMP, GLP, and GCP regulations. This individual will work with cross-functional teams to coordinate the Supplier Qualification Program as well as supporting the internal quality systems associated with GxP activities. This position will be integral in coordinating NDA readiness activities.

Responsibilities:

- Manage the Quality Supplier Qualification Program
- Support Quality & Compliance oversight for manufacturing, supply chain, clinical, & nonclinical activities across multiple Contract Organizations
- Assist in the execution of QA systems to support GxP from both an internal and external perspective
- Plan audit calendar, perform internal/external audits as required
- Support mock-PAIs and NDA readiness
- Support regulatory inspections, as required
- Review and aide in drafting Quality Agreements; review MSA/SOWs to verify alignment with Quality Agreements
- Write, review, and approve Standard Operating Procedures (SOP) and Forms for the organization
- Assist in build-out, management and continuous improvement of the QMS
- Trend and report QA related information (deviations, investigations, CAPAs) both internally and from external activities
- Review batch records and associated documentation, i.e., deviations, OOSs, investigations, specifications, etc.; lead internal investigations.
- Assist with other GxP programs and reviews as needed

Qualifications:

- BA/BS in Science
- Experience in a GxP regulated industry
- 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
- Ability to travel up to 25% of the time
- Auditor Certification
- Experience working in a small pharmaceutical company
- Experience working within a virtual manufacturing company utilizing a number of contract manufacturing organizations
- Experience in both internal auditing and in auditing Contract Organizations

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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