

Title: Manager/Senior Manager, Quality Assurance

Job Summary:

Reporting to the Sr. Director, Quality Assurance, the Manager/Senior Manager, Quality Assurance is responsible for the execution and administration of GXP Quality Systems, including support for Concert's Analytical Departments. The Manager/Senior Manager will work with cross functional teams to maintain the internal quality systems associated with GxP activities as well as interfacing with CMO/CROs.

Responsibilities:

- Review analytical protocols and reports, including associated documentation, i.e., deviations, OOSs, investigations, specifications, etc.
- Provide Quality oversight for Method transfer, qualification, and validation
- Perform Quality & Compliance oversight for manufacturing, nonclinical, clinical, & supply chain activities
- Assure consistency in achieving product quality and compliance across multiple CTLs and CROs
- Assist in build-out, management and continuous improvement of the QMS and SOP system
- Assist in the execution of QA systems to support GxP from both an internal and external perspective
- Perform and coordinate internal/external audits and monitoring visits
- 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 8 years' experience in GxP regulated industries
- Experience with HPLC LC/LC-MS
- Previous experience in setting specifications for API and Drug Product
- Extensive knowledge and experience in GXP and QA principles, practices & industry standards, experience with GLPs and preferred
- Experience using risk-based principles & decision making to ensure compliance at all stages of development
- 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

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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