

Title: Senior Director, Quality Assurance

Job Summary:

Reporting to the VP Regulatory Affairs & Quality Assurance, the Senior Director Quality Assurance is responsible for the strategy, implementation & leadership of the Quality function at Concert and is accountable for the execution and administration of the GXP Quality System pertaining to GMP, GLP and GCP and relevant ICH, US and EU regulations. This role will encompass all aspects of Quality Assurance, from strategic planning to hands-on implementation.

Responsibilities:

- Ensure overall Quality & Compliance oversight for manufacturing, nonclinical, clinical & supply chain activities.
- Establish & maintain phase-appropriate Quality Management Systems
- Ensure appropriate Quality oversight of external vendors (CMOs, CROs, etc)
- Oversight of Concert's internal Quality Systems training program.
- Plan & oversee day-to-day activities of the Quality function including management of consultants/auditors as needed, to ensure project & business needs are met.
- Develop and oversee appropriate Quality metrics and report on the state of Concert's compliance to senior management.
- Lead preparations for and management of any Regulatory Agency inspections
- Provide leadership & mentorship of the Quality team.

Qualifications:

- BS in Chemistry, Pharmacy, Biology or a related pharmaceutical science.
- 15+ years of progressive managerial experience within the Quality function of a pharmaceutical company. Experience leading a Quality function is required.
- Experience working in small biopharmaceutical company and/or experience working within a virtual manufacturing company utilizing a number of contract manufacturing organizations is preferred
- Extensive knowledge and experience in GXP and QA principles, practices & industry standards
- Experience with oral small molecule development programs, from early-stage through to commercial.
- A strong team player is required with the ability to effectively communicate sound Quality advice cross-functionally based on experience, regulations & business needs
- Experience with using risk-based principles & decision making to ensure compliance at all stages of development
- Proven track-record of leadership & building relationships with both internal & external customers
- Strong negotiation skills, flexibility & ability to provide a solution-based approach to emerging challenges.

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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