

**Title: Senior Manager/Associate Director, Clinical Operations**

**Job Summary:**

This is a critical role in the Clinical Development group at Concert. The Senior Manager/Associate Director of Clinical Operations will work closely with team members and be responsible for the planning and execution of assigned clinical studies.

**Responsibilities:**

- Responsible for overseeing the conduct of one or more concurrent Phase 1/Phase 2 clinical studies
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- Contribute to the development of the protocol including protocol writing if required
- Work directly with CROs, vendors, investigators, monitors, and other external partners as needed
  - Contribute to CRO/vendor selection
  - Coordinate tasks related to budgets and contracts
- Contribute to the review of all study related documentation (Investigator's Brochure, Lab and Pharmacy manuals, Informed Consent, Patient Diaries, Clinical Study Reports)
- Contribute to the development and review of data management related activities
  - Case report forms, User Acceptance Training, IVRS, Edit Check Plan, Data Management Plan, Monitoring Plan, Statistical Analysis Plan
- Work with Pharmaceutical Development and QA groups on the study drug quantity and packaging requirements
- Create Trial Master Files from Phase 1 studies as needed
- Contribute to the planning and execution of Investigator Meetings, Study Initiation Visits
- Review and contribute to development of department standard operating procedures
- Review and present clinical trial data at internal meetings
- Coordinate/lead team calls as needed, write and distribute minutes

**Qualifications:**

- Science background, BS/MS degree
- Approximately 7 years clinical research/operations experience in industry
- Strong knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials (Phases 1-3)
- Strong communication, leadership, interpersonal, organizational and multi-tasking skills
- Independently motivated
- Data Management and analysis skills a plus
- Excellent attention to detail and problem solving skills
- Ability to get project/task to the next step in an efficient manner
- Capable of changing direction quickly if needed
- Ability to work effectively/congenially in a team setting
- Aptitude for keeping project on time and within budget
- Travel as needed

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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](mailto:careers@concertpharma.com).

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