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## Clinical Trial Manager

The Clinical Trial Manager will oversee all steps in preparation for regulatory agency inspection. Specific accountabilities:

- Ensuring the Trial Master File (TMF) for selected studies are complete, current and ready for regulatory agency inspection
- Strong in clinical and regulatory compliance
- IND preparation and submissions
- Technical report writing SOP's, clinical reports
- Experience working with domestic and international regulatory agencies
- Reviewing documentation for completeness and accuracy, from study start-up through clinical study report publication
- Identifying document deficiencies
- Complying / updating lists of TMF contents
- Using checklists to assess TMF completeness and quality
- Collaborating with project team members to resolve TMF deficiencies
- Interacting with site staff to resolve ISF issues

**Requirements:** Due to the precise requirements of this position, candidates must meet all of the listed criteria. Requirements:

- 2+ years trial master file management experience is required; this includes setting up, maintaining and performing TMF reviews
- 1+ year of experience in a Clinical Trial Associate role
- Previous experience with inspection readiness analysis is preferred
- Minimum four years experience as Clinical Trial Administrator, Clinical Research Associate, or TMF GCP auditor
- Prior work on global clinical trial with understanding of complexity
- Advanced proficiency with MS Office Applications including Word, Excel, Outlook and PowerPoint is required
- Ability to learn and work with database and document management applications is required
- Proactive and able to work independently
- Ability to prioritize and multi-task with attention to detail
- Strong organizational skills
- Travel: 25% potential travel
- Team Player
- Multi-task