Reviewed By/Date: Name, Title	**Approved By/Date**: Name, Title

1. Job Summary

The Clinical and Regulatory Affairs Project Lead is responsible for contributing to the management of clinical trials from study start-up to completion and based upon CRS' contracted services with a client. The role includes multiple tasks of clinical and regulatory support, especially for ensuring the clinical trial is conducted in compliance with applicable regulations including current Good Clinical Practices (GCPs), and with CRS or client SOPs. In addition, non-traditional projects are performed and regulatory submission documents are prepared by the Clinical and Regulatory Affairs Project Lead. This role reports into the Director of Clinical and Regulatory Affairs. This role may also have supplementary reporting into a Clinical Project Manager who leads a trial.

2. Duties, Activities, and Responsibilities

2.1. Contributing to cross-functional regulatory and clinical teams, including clinical trials and other non-traditional projects in CRS' consulting practice.
2.2. Serving as key project lead on small studies with director oversight.
2.3. Helping to manage study start-up, trackers, sign-off, and study reports.
2.4. Helping to prepare agendas and meeting minutes.
2.5. Helping to write study plans, ICFs, sections of protocols, SOPs, literature reviews, study reports, IBs, User Manuals, IFUs, study training materials, recruitment materials and other study-related documents.
2.6. Developing study budgets under fair market value analysis.
2.7. Assisting with data integrity, data query and resolution issues.
2.8. Preparing IRB and regulatory agency submittal documents.
2.9. Preparing excel reports for CRF completion on small studies.
2.10. Assisting with the collection and maintenance of Essential Documents and tracking for Trial Master Files (TMFs).
2.11. Facilitating on-going communications with investigational sites and study teams.
2.12. Assisting with software specifications and participating in user acceptance testing of EDC.
2.13. Helping to manage study inboxes for TMFs and safety reports.
2.14. Collaborating with vendors.
2.15. Providing oversight of database maintenance, trial master file (TMF), and study trackers.
2.16. Developing meeting minutes and sign-off records.
2.17. Ensuring consistent use of study tools and training materials and compliance with standard processes, policies and procedures.
2.18. Assisting Quality Assurance with CAPAs, SOP revisions, audits, and inspections.
2.19. Additional tasks not described within to meet company requirements and Client milestones.

3. Education and Experience

3.1. A Bachelor's degree or equivalent in a life sciences or related discipline. Master's preferred.
3.2. Ideally three to five years of clinical research experience with increasing responsibility.
3.3. Alternatively, equivalent combination of education, training and experience in a life sciences environment.

4. Knowledge, Skills, and Abilities

4.1. Ability to meet deadlines for project team, Client, and vendors.

4.2. Continuous learning and training on ICH GCP, FDA, ISO, and international regulatory positions and updates.
4.3. Excellent professional written and verbal communication skills.
4.4. Excellent time management skills and attention to details.
4.5. Proven ability to be flexible and adaptable.
4.6. Ability to maintain relationships for repeat business.
4.7. Ability to write and modify SOPs, CAPAs, work instructions, forms, and templates.
4.8. Proficiency in Word, PowerPoint, Excel, and Outlook.
4.9. Demonstrated understanding of medical terminology and knowledge in therapeutic areas.