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

1. Job Summary

The Clinical and Regulatory Affairs Scientist is an integral part of the CRS clinical trials and management consulting teams. Under the supervision of the Director of Clinical and Regulatory Affairs and executive leads of the consulting business, the Clinical and Regulatory Affairs Scientist will support complex drug, biotechnology, and device writing assignments.

The Clinical and Regulatory Affairs Scientist brings specialized technical knowledge about the intersection of drug discovery, clinical research, and regulatory affairs to prepare clinical protocols, IND/IDE documents, grants, Investigator Brochures, annual reports (DSUR, PSUR), safety reviews, patient narratives, regulatory document submissions, and other clinical documents. The Clinical and Regulatory Affairs Scientist plays a critical role in liaising among staff supporting emerging clinical research programs, subject matter experts, and regulatory bodies. The Clinical and Regulatory Affairs Scientist translates scientific discovery into clinical practice by supporting researchers to develop study protocols and regulatory documents for treatments based upon work conducted at CRS. The Clinical and Regulatory Affairs Scientist also contributes to Regulatory Pathway Assessments (RPAs), abstracts, literature reviews, publications, and ad hoc writing assignments from time-to-time. The Clinical and Regulatory Affairs Scientist maintains adherence to ICH Good Clinical Practices, FDA guidelines, ISO standards, internationally-recognized biomedical writing standards, local regulations, and CRS Standard Operating Procedures.

2. Duties, Activities, and Responsibilities

2.1. Collaborating with the client's medical team to write the protocol, investigator brochure, informed consent form, recruitment materials, accompanying study-related documents and annual study reports.
2.2. Collaborating with client's medical team to produce literature reviews, clinical evaluation reports (CERs), abstracts and publications.
2.3. Collaborating with CRS regulatory team to write and manage modules for NDAs, MAAs, BLAs, PMAs, INDs, IDEs, HDEs, de Novo, and other regulatory submission documentation.
2.4. Writing FDA, EMA, and Health Canada briefing documents.
2.5. Writing and editing Risk Management Plans, Non-Clinical (Mod 2.4) and Clinical Summary (Mod 2.5) and accompanying tabulated summaries.
2.6. Coordinating quality control reviews of documents and maintaining audit trails of changes.
2.7. Providing input on data analysis planning and interpretation.
2.8. Writing ad hoc Client or CRS company documentation on an as needed basis.
2.9. Ensuring consistent use of writing tools and training materials and compliance with standard processes, policies and procedures.
2.10. Ensuring sign-off of versions by Clients.
2.11. Assisting Quality Assurance with CAPAs, SOP revisions, audits, and inspections.
2.12. Additional tasks not described within to meet company requirements and Client milestones.

3. Education and Experience

3.1. A PhD, MD, or PharmD or equivalent in a life sciences or related discipline.
3.2. Ideally five years of clinical research experience writing study related documents.
3.3. Expert use of American Medical Writers Association (AMWA) and similar industry writing guidelines.

4. Knowledge, Skills, and Abilities

4.1. Continuous learning and training on ICH GCP, FDA, ISO, and international regulatory positions and updates.
4.2. Proficiency in Word, PowerPoint, Excel, and Outlook.
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. Valid driver's license.
4.9. Demonstrated understanding of medical terminology and knowledge in therapeutic areas.
4.10. Familiarity with medical coding.
4.11. Expert use of EndNote, Starting Point templates and other reference tools.