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

1. Job Summary

The Associate Director of Clinical and Regulatory Affairs will be responsible for overseeing and managing client programs for Clinical Research Strategies (CRS) under best business and ethical practices, and applicable regulations including current Good Clinical Practices (GCPs) and ISO14155. This role is autonomous and involves the highest level of critical-thinking, flexibility, teamwork, and client relations. The Associate Director of Clinical and Regulatory Affairs serves in multiple facet roles including leading project teams and/or assuming leadership roles on a clinical trials team for the duration of a project. Other projects may include non-traditional programs. This position has dual reporting responsibilities to the Director and the President.

2. Duties, Activities, and Responsibilities

2.1. Adherence to US laws and regulations, business ethics, corporate and financial compliance, confidentiality, and industry-wide best practices.
2.2. Facilitation of contracts, monthly/milestone invoicing, and payments.
2.3. Production of SOPs, RFPs, gap analyses, TMF audits, written policies, regulatory positions, presentations, investor decks, training programs, and white papers, IND, IDE, Q-Sub regulatory materials.
2.4. Presentation of capabilities and bid defenses to prospects and clients.
2.5. Conduct upfront and routine risk analyses to proactively identify program risks.
2.6. Collaboratively implement risk mitigation strategies to ensure successful delivery of program goals.
2.7. Provide oversight for development and implementation of project plans in accordance with SOPs and regulations.
2.8. Contribute to strategy for IND- and IDE-enabling drug and device products, submissions, and clinical trials.
2.9. Preparation of fair market budgets (FMV) and realistic forecasts with disciplined spend.
2.10. Application of GxP regulations and requirements to projects.
2.11. Quality-driven management and oversight of vendors and CROs.
2.12. Perform research for and participate in capability presentations of technology provider innovations that reduce costs to clients.
2.13. Write protocols, ICFs, IBs, CERs, CEPs, Literature Reviews, IFUs, User Manuals, CSRs, patient fact sheets or recruitment materials, and other study-related materials.
2.14. Create electronic files and maintenance of documentation in a regulatory-compliant and cyber-secure environment.
2.15. Interface with regulatory officials, investors, business partners, and client executives.
2.16. Development and management of client relationship management (CRM) system.
2.17. Spearhead projects to completion.
2.18. Creation of routine status reports for clients.
2.19. eTMF and paper TMF expertise, set-up, oversight, audits.
2.20. Serve as Senior Clinical Project Lead for Sponsors, CROs, and CRS when needed.
2.21. Oversee project management and project manager activities for clinical trial programs.
2.22. Define program requirements and timelines.
2.23. Conduct feasibilities.
2.24. Recruit, screen and interview talent for CRS and/or for clients.
2.25. Manage and train teams.

2.26. Create RFPs for Sponsors undergoing CRO selection.
2.27. Prepare meeting minutes or notes.
2.28. Assist with business operations.
2.29. Proficiency in software applications such as Outlook, Word, Excel, Visio, PowerPoint, Project, SharePoint, etc.

3. Education and Experience

3.1. Advanced degree with 7+ years of industry experience.
3.2. 5-10+ years of experience with project management in life sciences industry.
3.3. Experience writing protocols, informed consents, protocol-related documentation, proposals, quotes, business plans, SOPs, policy, capability presentations, bid defenses, and gap analyses.
3.4. Critical thinking, problem-solving, and fact-finding.
3.5. Regulatory review and writing.
3.6. Leadership aptitude for overseeing high-performing teams.

4. Knowledge, Skills, and Abilities

4.1. Required thorough understanding and knowledge of documentation, records management, and regulatory conformity in support of GCP regulations and best business and ethical practices.
4.2. Demonstrated ability to communicate effectively (verbal and written) across cross-functional divisions and vendors internally and with key clients and stakeholders externally.
4.3. Proven ability to lead the initiation of clinical research programs and building of quality results over the life of a clinical trial.
4.4. Expert at time management and deliverables.
4.5. Expert at presentations to wide audiences.
4.6. Oncology, precision medicine, medical devices, and regenerative medicine experience preferred.
4.7. NIH, NCI, and DoD grant experience preferred.