



Position	Regulatory Medical Writer
Prerequisites	Minimum of BS/BA degree in science (MS/PhD/PharmD preferred) with approximately 1-3 years of regulatory writing and submission experience
<p>Responsibilities will include, but are not limited to, the following:</p> <ol style="list-style-type: none"> 1. Author, co-author, critically edit, and format regulatory documents including protocols, CSRs, Investigator Brochures, briefing documents, NDAs, MAAs, INDs, DSURs, and other regulatory submissions; 2. Author, co-author, and critically edit publications including abstracts, posters, slide presentations, manuscripts, and review articles; 3. May manage overall medical writing timelines for assigned projects; 4. Serve as the lead on assigned projects and advise teams on content, format, and style-guide requirements for documents; 5. Support the development of medical writing processes, SOPs, work instructions, and document quality control; 6. Maintain subject area expertise relating to the client's investigational products, disease indications, and regulatory and publication guidelines; 7. Willingness to perform miscellaneous job-related duties as assigned and accept new responsibilities as needed. <p>Additional qualifications may include:</p> <ol style="list-style-type: none"> 1. Excellent ability to interpret and present scientific and clinical trial data and understand statistical analyses; 2. Excellent writing skills coupled with knowledge of the drug development process and regulatory guidelines; 3. Effective collaborator with ability to foster strong working relationships and build consensus among colleagues on cross-functional teams; 4. Initiative and ability to handle a variety of projects simultaneously; 5. Excellent interpersonal and communication skills; 6. Advanced knowledge of clinical and regulatory documents and publication practices including GCP, ICH, ICMJE, and CONSORT; 7. Expert user of Microsoft Word, PowerPoint, and Excel; and 8. Tech-savvy with the initiative and drive to support the implementation of software solutions to streamline medical writing processes 	