JOB DESCRIPTION			
Company:	QED Therapeutics, Inc.		
Employee:			
Role Title:	Senior Medical Writer	FLSA Status:	Exempt
Reports To:	Laurie Haynes, Exec Dir, Medical Writing		
Department:	Project Management		
Position Summary:	The Senior Medical Writer develops, writes, and edits clinical/regulatory documents (such as clinical study reports [CSRs], clinical protocols, investigator brochures, regulatory briefing documents, and CTD Module 2 summaries), both independently and with teams. Builds strong working relationships with Clinical Development, Regulatory Affairs, Nonclinical, Safety, and other collaborators.		
Job Responsibilities:	● Provides broad medical writing and project management support for the Clinical Development and Regulatory Affairs groups. This is a hands-on position that entails writing and editing clinical documents for submission to regulatory authorities. ● Prepares, and manages timelines for, the following documents: briefing documents, clinical development plans, investigator's brochures, clinical study protocols and amendments, CSRs, patient narratives, CTD clinical overviews and summaries, safety updates, integrated summaries of safety and efficacy, and other clinical/regulatory documents as needed. ● Participates in electronic document publishing efforts. Initiates and manages development of formats, templates and general guidelines for clinical documentation and workflow procedures. Ensures document content and style adhere to ICH/FDA/EMEA or other appropriate regulatory guidelines, and complies with departmental and corporate SOPs and style guidelines ● Assists in the development of SOPs and guidelines ● Facilitates internal review of documents and consolidates comments from internal and external reviewers or writers ● Performs literature searches to obtain background information for development of documents		

Preferred Qualifications:	• Bachelor's degree with a minimum of 8 years, Master's with a minimum of 6 years, or a MD, PharmD, or PhD with a minimum of 5 years experience in the research, pharmaceutical or biotechnology industry (including postdoctoral work) • Strong scientific/medical/health-related background • Experience must include at least 3 years of relevant medical writing industry experience and a proven track record in writing high quality regulatory documents • Experience in writing clinical and regulatory documents for oncology products is a plus but not essential • Strong written and oral communication skills • Ability to analyze, interpret, and communicate data concisely • Exceptional organizational and project management skills • Demonstrated knowledge and understanding of business processes, regulatory, and other requirements (GCP, eCTD, ICH, etc.) • Experience with and working knowledge of clinical trials, clinical development, biostatistics, regulatory, legal. • Self-motivated and flexible; ability to set objectives and deliver quality results in a dynamic, fast-paced environment • Expert user of Microsoft Office word processing, presentation, and spreadsheet software; electronic publishing software, such as Adobe Acrobat • Proficient with scientific graphing and database software • Comfortable with computer programs and has the ability to master new programs in a limited amount of time