JOB DESCRIPTION			
Company:	QED Therapeutics, Inc.		
Role Title:	Director / Sr. Director, Clinical Operations, Oncology	FLSA Status:	Exempt
Reports To:	VP, Clinical Operations		
Department:	Clinical Operations		
Position Summary:	The Director/Sr. Director, Clinical Operations will be responsible for coordination and implementation of clinical operations activities of multiple clinical trials. In addition, he or she will be responsible for properly resourcing, managing and executing clinical studies within budget and in accordance with established timelines and quality standards.		
Job Responsibilities:	• Study Planning and Management. Coordinate and actively participate in the development and updating of study-related documents (investigator brochure, clinical protocols, informed consent forms, case report forms, clinical study reports, amendments, adverse event reporting, site training manuals) and analysis plans (including data collection and management); Monitor study progress and maintain timeline from initiation through publication of study results; work very closely with the clinical lead to advance the studies. • Quality control. Responsible for development, training, implementation and compliance of Standard Operating Procedures; Develop quality control processes and monitoring plans to ensure that all clinical activities are compliant with Good Clinical Practices and regulatory guidelines. • Clinical Trial Budgeting. Work with finance department on the development and negotiation of trial site budget and clinical trial agreements; Forecast and manage clinical trial budgets and FTE costs; Ensure accurate accruing of study costs; Review vendor invoices against contract and work completed; Oversee reconciliation of site payments against patient visits to ensure accurate payments; Identify and communicate variances. • Trial Site Management. Cultivate and maintain strong relationships with investigators, and trial site administrators; Organize investigator meetings as needed; Lead effective communications with trial sites for specimen tracking, study conduct and timely data review to identify trends and discrepancies; Contributes to development of abstracts, presentations and manuscripts for studies.		

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	• Vendor Management. Responsible for collection and preparation of all information needed to facilitate selection, on-boarding and management of CRO and vendors for outsourced activities; develop statements of work, budgets and timelines; Responsible for gap analysis, performance management, risk management and issue resolution. • Supply Chain Management. Coordinate and plan for availability of clinical and non-clinical supplies required for trial execution • Other duties as assigned.		
Preferred Education and Experience:	• BA required in a scientific/medical field. Advanced degree preferred. • At least 10 years (confirm) of experience in clinical operations within the biopharma industry • At least 7 years of management experience in a clinical research environment • Demonstrated ability to successfully develop, implement, manage and complete oncology clinical trials on time and on budget • Expert working knowledge of study initiation, execution, analysis and closing procedures • Intimate knowledge of GCP and strong working knowledge in FDA, Good Clinical Practices and ICH regulations and guidelines and the application to the conduct of clinical trials • Experience in cell therapy or stem cell transplant clinical trials preferred • Experience with investigator-initiated and industry-sponsored studies • Experience in Quality Assurance, SOP writing, CAPA preparation and successful closure • Experience in working with clinical trial teams, including data management, clinical sciences, medical monitors, regulatory and QA • Excellent leadership, organizational and multi-tasking skills in a fast-paced start-up environment • Very dynamic and energetic, hands on approach to the challenges • Excellent written and verbal skills and strong interpersonal skills required • Deep understanding of clinical trial design, protocol development and review, running the clinical trial meetings		

Please submit your resume to careers@qedtx.com. For more information, or to learn about QED Therapeutics, please visit www.qedtx.com.