JOB DESCRIPTION	
Company:	QED Therapeutics, Inc.
Employee:	TBD
Role Title:	Associate Director/Director, Inspection Readiness
Reports To:	Vice President, Quality Assurance
Department:	Quality Assurance
Company:	A subsidiary of BridgeBio, QED focuses on precision medicine for FGFR-driven cancers and diseases. QED is devoted to the development of our investigational candidate, infigratinib. A first-in-class, selective, tyrosine kinase inhibitor, infigratinib has promising early clinical data in patients with previously treated, FGFR-driven cholangiocarcinoma and metastatic urothelial carcinoma, as well as preclinical studies in achondroplasia. Future studies will investigate infigratinib for additional FGFR-driven tumor types and rare disorders.
Position Summary:	QED is seeking a highly-motivated, full-time contract Associate Director/Director of Inspection Readiness, who is a collaborator and enjoys a fast-paced, dynamic work environment. The ideal candidate has experience as a Quality and/or Clinical professional who has prepared an organization for regulatory authority inspections as the result of an NDA filing/marketing application. This position will collaborate with the inspection readiness leads of the Quality, Clinical, and CMC teams to ensure inspection readiness at QED, CROs, and clinical sites; and ensure pre-approval inspection readiness at CMOs.
Job Responsibilities:	• Define, lead, and track inspection readiness activities/goals for QED • Lead and participate in inspection readiness site visits • Participate in cross-functional teams to identify and champion GCP/GLP/GMP inspection readiness activities to defend business processes • Proactively identify gaps in QED practices, policies, and procedures, and prioritize based on current regulatory environment, guidelines, and regulations • Support efforts to remediate or defend identified inspection risks • Support logistic and strategic planning and support during inspections (e.g., war room support, strategize and review inspection requests, inspection room support) • Lead partnerships with key stakeholders to deliver solutions and training to facilitate maintenance of ongoing state of inspection readiness • Organize electronic and paper files to ensure inspection readiness and document retrieval during an inspection • Assist in the creation of an opening presentation for regulatory authority inpsections • Outline BIMO preparation and story boarding along with pre-approval inspection readiness

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	• Participate in the authoring and review of department policies and procedures • Perform any other tasks as requested by Management to support Quality oversight activities
Preferred Education, Experience and Skills:	• BA/BS degree in life sciences, engineering or a related discipline required • 7+ years of direct GXP pharmaceutical/biotechnology experience • 5+ years of management experience in a clinical research environment • Experience with regulatory authority inspections, including both FDA and EMA inspections • Solid understanding and application of GCP/GLP/GMP and ICH requirements; experience with GCP/GLP/GMP auditing practices • Familiar with all phases of small molecule drug development • Experience working in a start-up or fast-growing company preferred • Demonstrated high personal and professional ethical standards • A well organized, self-motivated, and independent work style with the ability to initiate and follow through on assignments • Outstanding verbal communication skills which resulted in professionally communicating and guiding individual and team efforts related to inspection readiness • Ability to build relationships and work collaboratively with a variety of individuals within the department, company, and external vendors • Apply advanced theory, technical principles, expert judgement, and cross-functional expertise to independently address unusual complex topics/situations • Ability to simultaneously handle multiple project issues while dealing with time demands, incomplete information, or unexpected events • Experience using risk-based principles and decision making to ensure inspection readiness • Proven track-record of leadership and building relationships with both internal and external customers • Strong negotiation skills, flexibility, and ability to provide a solution-based approach to emerging challenges • Ability to travel to clinical sites and vendors for inspection readiness activities • Other skills and abilities as required

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