ALLIANCE
FOUNDATION TRIALS, LLC

125 S. Wacker Drive, Suite 1600 • Chicago, IL 60606
P: 773-702-9171 • F: 312-345-0117
AllianceforClinicalTrialsinOncology.org

Job Description			
Job Title:	**Quality Associate**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Quality Management	**Reports to:**	Director of Quality Management
Location:	Boston	**Travel Required:**	<20%
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐
HR Contact:	Human Resource Director	**Date posted:**	Click here to enter a date.
External posting URL:	Click here to enter text.		
Internal posting URL:	Click here to enter text.		

Alliance Foundation Trials, LLC (AFT) sponsors and conducts high-quality cancer clinical trials funded exclusively by non-NCI (National Cancer Institute) sources. AFT leverages the internationally recognized scientific experts and thought leaders of the Alliance for Clinical Trials in Oncology with its expansive and established network of hospitals, medical centers, and community clinics across the North America.

In May 2014, the Foundation created Alliance Foundation Trials, LLC (AFT), which is a wholly owned subsidiary of the Foundation. It was also created to conduct cancer clinical research and address medical care and treatment through large-scale clinical trials involving various industry-related partners.

Purpose/Scope:

Alliance Foundation Trials, LLC (AFT) is currently seeking Quality Associates at multiple levels of experience. AFT and all our affiliates and interrelated organizations were created to conduct cancer clinical research and address medical care and treatments involving various industry partners and various stakeholders. Quality Associates are generally responsible for managing the clinical quality and compliance functions of the organization. The QA is responsible for planning, coordination, control, and continuous improvement of processes and methods established to control the quality of studies conducted by Alliance Foundation Trials, LLC. The Quality Associates' role is focused on continuous improvement projects using approved tools, design control, validations, and ensuring adherence to the agency regulations, GxP, ICH GCP, Industry Guidelines, local regulations, along with AFT policies and procedures for the conduct of clinical trials. This involves working closely with clinical operations, information technology, and other supporting areas/development teams, to help ensure active participation in continuous quality improvement activities.

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ROLE AND RESPONSIBILITIES

Depending upon qualifications and experience, Quality Associates may be asked to participate or lead the following activities.

- Development and maintenance of GCP/ICH compliant processes and Standard Operating Procedures (SOPs) which control the quality of work and clinical trials conducted by AFT
- Periodic reviews of AFT's policies and procedures; assist functional teams in identifying process improvements and developing appropriate policies and procedures to support the work being conducted
- Preparation for audits and inspections at AFT and coordinates the activities of the AFT Inspection Readiness Team (IRT).
- Internal Quality Audits, CAPA (Corrective and Preventative Actions), Quality Management Reviews, and Quality Audit, in conjunction with the AFT Clinical Trial Auditor and other AFT staff.
- Draftng and implementing audit plans for internal process and trial master file audits.
- Assist in auditing activities to ensure that studies are conducted in accordance with sponsor protocols, GCP, industry guidelines, agency regulations
- Develop and/or deliver training on health authority regulations, GCP, and inspection readiness to Alliance Investigators and internal AFT staff. Supports key quality processes, metrics and indicators to measure trend and improve key quality determinants of all aspects of GCP and support GxP operations
- Review TPO supplied data and quality records for conformance and good documentation practices (GDP)

QUALIFICATIONS AND EDUCATION REQUIREMENTS

BA/BS in associated functional discipline

- At least 2 years' experience in the Pharmaceutical Industry with in depth knowledge of US, EU, and International regulatory standards, and GxP Guidelines for the conduct of clinical trials
- 1+ years working in a Quality Control/Assurance area
- ASQ, Auditor, CCRP, or ACRP accreditation preferred.
- Experience including external/CRO, clinical/regulatory and document auditing preferred.

Last Updated By:	Heather Choukri	Date/Time:	July 12, 2019

Employee Name: Date:

Employee Signature: _____