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

Job Description			
Job Title:	**Auditor, Quality and Compliance**	**Job Category:**	Exempt ☒ Non-Exempt ☐
Department/Group:	Alliance Foundation Trials, LLC (AFT)	**Reports to:**	Quality Manager
Location:	Chicago or Boston Office	**Travel Required:**	60-70%
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☐ Temporary ☐
HR Contact:	Director of Human Resources	**Date posted:**	
External posting URL:			
Internal posting URL:			

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY FOUNDATION'S MISSION:

The Alliance for Clinical Trials in Oncology Foundation (Foundation) is a nonprofit, tax-exempt foundation created to enhance and expand the ability of the Alliance for Clinical Trials in Oncology (Alliance) to conduct cancer clinical research and address important treatment questions through large-scale clinical trials. Through efforts of the Foundation in support of the Alliance, clinical trials and laboratory research are conducted to discover new or improved ways to prevent, treat and cure many types of cancer, including leukemia and lymphoma, and cancers of the breast, prostate, lung and GI tract, and help educate the medical community on methods of cancer diagnosis, treatment, and prevention.

In May 2014 and February 2015, the Foundation created the Alliance Foundation Trials, LLC (AFT, LLC) and Mastering Breast Cancer, LLC (MBC, LLC), respectively, which are wholly owned subsidiaries of the Foundation. These entities were 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:

The auditor will report to the Director, Quality and Compliance and conduct clinical study audits at investigator sites and third party organizations (TPOs).

ROLE AND RESPONSIBILITIES

- Lead qualification, routine and for-cause audits of TPOs and investigator sites to assess effectiveness of quality management systems (QMSs), compliance to approved clinical study protocols, and contracts.
- Ensure timely issuance of audit reports, audit observation forms, oversee audit response process and drive audits to closure
- Maintain and enhance procedures for communicating audit observations and tracking audit responses
- Contribute to identified quality and compliance process improvements
- Support Quality and Compliance department trending
- A minimum 60-70% travel is required to conduct investigator site and TPO audits.

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QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Education:
  - Bachelor of Science or Bachelor of Arts degree required, preferably in a relevant scientific discipline.
- Computer Skills:
  - Proficient in MS Office suite (MS Office products, word processing, spreadsheets, internet, e-mail)
- Related Experience:
  - 5 Years GCP QA auditing/monitoring experience in an FDA regulated industry, Pharma or Biotech preferred

ADDITIONAL NOTES

Candidates must demonstrate the following competencies:

- Manage interpersonal relationships by interacting and communicating with clarity, tactfulness and courtesy with internal and external personnel
- Communicate effectively, both orally and in writing
- Organizational and prioritization skills
- Work effectively as a part of a team and independently with minimal supervision.
- Ability to work under pressure and coordinate multiple tasks
- Attention to detail
- Time management, multi-tasking, problem solving, and effective communication skills

Approved By:	Click here to enter text.	Date:	Click here to enter text.

Employee Name: Date:

Employee Signature: _____