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:	**SOP Writer**	**Job Category:**	Exempt ☐ Non-Exempt ☐ Contract ☒
Department/Group:	Quality Management and Compliance	**Reports to:**	Quality Manager & Research Manager
Location:	Boston	**Travel Required:**	Possible
Level/Salary Range:	$	**Position Type:**	Full-Time ☒ Part-Time ☐ Contract ☒ Temporary ☒
HR Contact:	Heather Choukri	**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:

The SOP (Standard Operating Procedures) Writer, under the direction of the Chief Operating Officer and the Director of Quality Management and Compliance (QMC) is responsible for working with AFT and Alliance Subject Matter Experts (SMEs) to prepare new or revised, SOPs, and Work Instructions (WINs) as part of an overall document creation and integration project in a cancer clinical research environment.

ROLE AND RESPONSIBILITIES

- Research and document clinical trial operations policies, processes and procedures by meeting with SMEs in QMC, Clinical Trials Operations (CTO), Business Systems Analytics (BSA) and Contracts Administration (CA).
- Coordinate and setup meetings with appropriate individuals: Directors, Managers, Project Managers and Clinical Research Associates and Coordinators as well as Systems Analysts.
- Draft SOPs WINs and related policy documents for review and approval.
- Identify process for interviewing SMEs and distributing documents for review and comment; identify process for incorporating suggested and final edits to documents.
- Assess feedback from multiple reviewers and work with the QMC Director to resolve competing comments and revisions. Integrate final comments and edits into next draft.
- Produce compliant SOPs, WINs and other controlled documents, as assigned.

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- Post controlled documents to document management software
- Working with BSA draft WINs for new doc management system maintenance.
- Identify, communicate and follow-up on recommendations and noted deficiencies in document content.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Bachelor's degree in English, Technical Writing, Communication, or Science and Engineering with writing emphasis.
- At least 2 years of SOP/WIN/Grant research and writing experience.
- Must have strong time management skills to lead SMEs through the simultaneous revision and development of multiple documents while adhering to defined timelines."
- Excellent verbal and written communication skills, including ability to interview SMEs and identify significant processes and procedures.
- Excellent presentation skills; ability to inform and educate regarding the process to be followed and expectations from SMEs.
- Remote employees must be willing to travel to Boston, MA at least once per month for the period of assignment.
- Microsoft Suite (Word, Excel, Power Point, etc.) proficiency required

PREFERRED SKILLS

- Prior experience writing documents in the cancer clinical trials environment highly preferred.
- Experience in the Pharmaceutical Industry/Clinical trials with in depth knowledge of US, EU, and International regulatory standards, and GxP Guidelines for the conduct of clinical trials is strongly preferred
- Experience with document management/control software applications preferred.

ADDITIONAL NOTES

[Type any additional notes if needed.]

Reviewed By:	Click here to enter text.	Date:	Click here to enter a date.
Approved By:	Click here to enter text.	Date:	Click here to enter text.
Approved By:	Click here to enter text.	Date:	Click here to enter a date.
Last Updated By:	Click here to enter text.	Date/Time:	Click here to enter text.

Employee Name: Date:

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Employee Signature: _____