

Job Description			
Job Title:	Project Coordinator, Quality	Job Category:	Exempt <input type="checkbox"/> Non-Exempt <input type="checkbox"/>
Department/Group:	AFT Foundation	Reports to:	Quality Manager
Location:	Boston	Travel Required:	No
Level/Salary Range:	\$	Position Type:	Full-Time <input checked="" type="checkbox"/> Part-Time <input type="checkbox"/> Contract <input type="checkbox"/> Temporary <input type="checkbox"/>
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.		
<p>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.</p>			
<p>Purpose/Scope: The Project Coordinator is responsible for coordinating and supporting activities of the AFT operations, quality and regulatory compliance teams with a primary assignment to the quality unit.</p>			
<p>ROLE AND RESPONSIBILITIES</p> <ul style="list-style-type: none"> • Coordinate and facilitate activities related to Standard Operating Procedure (SOP) development and training, including quality control of documents, and assignment of training in Learning Management System based on employee training matrix • Assist in the maintenance and auditing of employee training records • Assist in coordination of on and off site in person trainings for AFT employees and external resources • Assist with tracking of study specific training and maintain vendor management trackers • Support external vendor meeting coordination including agendas/minutes and routine correspondence • Assist in the production of training presentation/slides • Maintain Quality and other relevant documents in the AFT Document Management System (DMS); ensure documents are filed appropriately • Serve as administrator for the AFT Trial Master File and Learning Management System (LMS) • Assist with TMF audits • May act as the administrator and/or assist with other AFT clinical trial management systems, as assigned • Develop reports for quality metrics and other AFT site or study management reports, per requirements from AFT quality, regulatory and operations staff • Assist with regulatory submissions to regulatory authorities and study registrations in ClinicalTrials.gov and other required registries 			

- Support audit and inspection activities

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Bachelor’s degree and relevant work experience (pharma, biotech, CRO preferred)
- Demonstrated working knowledge of GCP, ICH guidelines and FDA regulations.
- Demonstrated ability to work independently and in a team environment.
- Proficiency with MS Office (e.g. Word, Excel, PowerPoint, Outlook).
- Excellent oral and written communication skills, and strong organizational abilities. <

PREFERRED SKILLS

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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:

Employee Signature: _____