Clinical Research Quality Assurance Auditor

Position Location: **401 North Washington Street, 7th Floor, Rockville, MD 20850**
Job Code: **TAL-QAA**

Description

The Emmes Corporation, organized in 1977, is a privately owned Contract Research Organization (CRO) located in Rockville, Maryland. Emmes is dedicated to providing statistical and epidemiological expertise, computer systems development, data management, study monitoring, regulatory guidance, and overall operational support to clients engaged in clinical and biomedical research.

Emmes is seeking a Clinical Research Quality Assurance Auditor to support all phases of clinical trials.

Purpose

The Clinical Research Quality Assurance Auditor will assist in the management of overall quality, compliance, and auditing activities to ensure compliance of operations with corporate policies, industry standards, and applicable regulations (GCP) by conducting audits of Emmes projects, processes, and vendors used to support clinical trials.

Primary Purpose

- Assist in various quality improvement initiatives in order to comply with Good Clinical Practice (GCP) requirements, SOPs, and applicable regulations
- Work closely with the QA Administrative Coordinator and the Quality Management Representative in support of Emmes's corporate Quality Assurance Department

Primary Responsibilities

- Conduct audits to identify non-compliance in adherence to SOPs, regulations, and GCPs Provide GCP/QA consultation to Emmes staff
- Write/revise SOPs, as needed
- Manage the employee training records
- Assist in the management of the CAPA programs
- Review Quality Records for accuracy and compliance (Compliance with SOPs, training records, test plans/scripts, CAPAs, audit reports)
- Support supplier/vendor qualifications and evaluations
- Support Change Control Board quality system/validation representation
- Support regulatory/client audits
- Assist in preparation of Quality Management Reports
- Drive completion of quality compliance plans
- Assist in the creation of quality metrics to report to senior management

Requirements

- Clinical trial auditing and clinical quality assurance experience is required, other QA experience will not satisfy job requirement
- BS degree in science-related field preferred or equivalent years of experience in clinical trial auditing and clinical quality assurance
- Certified Quality Auditor, ISO, CCRA, or equivalent certification preferred
- An in-depth knowledge and experience in the application of good clinical practice (GCP) requirements is required (eg, ICH, FDA, etc), as is familiarity with the essential documents related to clinical research studies
- Experience in GCP auditing activities thorough hands on experience of ICH-GCP and appropriate regional clinical research regulations and guidelines required
- Strong written and oral communication skills essential
- Ability to work with others, as well as independently
- Ability to multi-task, excellent organizational skills
- Enjoy working in a team environment

Emmes has an outstanding benefits package including: generous tuition reimbursement, professional development and training programs.

***For immediate consideration please submit your resume and apply directly through the company website at www.Emmes.com** .

Please visit our website at www.Emmes.com for additional information on our company, studies and history.

CONNECT WITH US!!

Follow us on Twitter - @EmmesCorp
Find us on LinkedIn - The Emmes Corporation

Emmes is proud to be an Equal Opportunity Employer EOE/M/F/D/V