GCP QA Auditor

Location: Stirling (FK9) (office based)

Salary: £COMPETITIVE

Job type: Permanent

Company: The CLINICAL TRIAL Company™

An exciting opportunity has arisen for an experienced GCP Quality Assurance Auditor to join The CLINICAL TRIAL Company™ Ltd (TCTC), a world-leading full-service clinical research organisation (CRO).

TCTC has offices in the UK, Canada, Australia, Singapore and the USA. We operate throughout Europe, North America, South America, India, China, Africa and Australasia. Our expanding company provides clinical trial services and support to the pharmaceutical and medical device sector.

We are seeking an experienced GCP QA Auditor to join The CLINICAL TRIAL Company to conduct GCP external and internal audits based on TCTC's audit programme, or as required by a sponsor. This position will report to our QA Manager and the position will be based in our Scottish office in Stirling.

Essential duties and responsibilities include, but are not limited to the following:

- Schedule, prepare and conduct GCP audits of clinical investigator sites, vendors, databases, clinical laboratories, and CROs
- Ensure compliance to protocols, procedures and regulatory requirements
- Produce descriptive and detailed audit reports
- Categorize and classify audit observations
- Propose effective and efficient CAPA, where applicable
- Conduct CAPA follow ups, where applicable
- Perform trend analysis
- Liaise with TCTC departmental heads to support implementation of business improvement initiatives

Description
The role will require you to be educated to degree level or equivalent in a scientific field with broad global clinical QA experience within a CRO or pharma company; 2 years proven GCP experience; a full driving licence together with a willingness to travel in Europe, North and South America. The role requires:

- Experience in Investigator Site Audits of GCP clinical trials
- Experience in preparation for/hosting of Sponsor Audits and Regulatory Inspections
- Good working knowledge of technical concepts required for GCP auditing
- Knowledge of pharmaceutical/biotechnology process and auditing standards
- Sound knowledge of GCP regulations and guidelines, as well as GLP and GCLP
- Ability to interpret and apply regulatory requirements
- Strong attention to detail and excellent time management skills
- Excellent oral, written and interpersonal communication skills required
- Ability to effectively communicate and successfully manage conflict
- Full driving licence together with a willingness to travel

GCP QA Auditor

This is an exceptional opportunity within a career driven and progressive organisation offering excellent salaries and benefits.

TCTC offers prospective candidates a truly exciting opportunity to join a growing and dynamic organisation, developing your career as the company grows. TCTC's employees are vital to our success and so we are looking for candidates to join the company and to stay and grow with us. In return you will be rewarded with the opportunity to work on clinical trials of real scientific merit and with excellent opportunities for professional and personal development.

KEY WORDS: GCP; Good Clinical Practice; Quality Assurance; QA; Auditor; GxP

For further information on the role please contact:

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Ref: GCP QA Auditor – Stirling

WE ARE SORRY BUT WE DO NOT ACCEPT APPLICATIONS FROM RECRUITMENT COMPANIES