



TRIAL FORM SUPPORT

GCP Auditor

A GCP auditor is part of the Quality Assurance Unit, and works in the planning, execution and completion of both national and international clinical trial audits. The Quality Assurance Unit is responsible for developing, updating and securing the internal quality of the operational units. Quality assurance is also performed as an external activity on behalf of our clients.. The work often involves cooperation with colleagues at our other offices.

Principal duties relate to:

- Preparing and conducting internal and external audits to ensure compliance with protocols, relevant SOPs and applicable regulations and guidelines
- Preparing investigational sites for inspection by regulatory authorities
- Facilitating customer audits of the company and/or projects
- Training other quality assurance personnel as required
- Assisting with training and advising company and client personnel on GCP (Good Clinical Practice), SOPs and quality assurance requirements
- Assisting with business development of external quality assurance services
- Developing new and existing quality assurance SOPs.

Desirable qualifications and background:

- Relevant academic education in life sciences or equivalent experience
- Minimum of three years experience in clinical research
- Minimum of one years experience as GCP auditor
- Excellent knowledge of regulatory requirements and the clinical research process
- Ability to independently deal with complex and difficult situations
- Good organisational skills
- Good communication skills
- Ability to prioritise and handle simultaneous work-tasks