ARC REGULATORY LIMITED

JOB DESCRIPTION

Job Title: Head of Global Research Compliance

Reporting To: CEO/Director

Salary: £ DOE

Job Purpose: To take full ownership of the company's Clinical Research Quality Assurance service provision (clinical quality operational support, strategy development, quality reporting etc.), working as part of the Senior Management Team to ensure Clients' medical device clinical research is conducted in compliance with global GCP standards, that the company's research quality assurance consulting business unit is operating at an optimum level of expert performance and that robust plans are implemented to enable to department to respond effectively to increasing client needs in a constantly evolving regulatory landscape.

Key Responsibilities:

- Take a full leadership role in the company's Research Quality Assurance business, including P&L responsibility, budget setting and opportunity identification.
- Play an active role in the formulation and implementation of the short, medium, and long-term business strategy and the development of KPIs that allow for measurement of success.
- Champion a culture of quality within the company and with sponsor research laboratories/sites.
- Contribute to the ongoing improvement and maintenance of the Company QMS in compliance with ISO 13485 and other international standards and requirements for medical device research.
- Plan and conduct, in collaboration with the Quality lead, routine and risk-based Quality audits and inspections of the ARC QMS, in order to provide assurance of compliance with the ARC QMS documentation.

- Plan and conduct routine and risk-based audits and inspections of client sponsor clinical study sites/vendors in order to provide assurance of compliance with relevant GCP, QMS documentation, applicable standards, regulations and guidelines, as required by client.

- Ensure audit results and other quality information are formally and consistently recorded and reported and that corrective actions/preventive actions are documented effectively.

- Oversee the documentation and tracking of Research Compliance activities, including deviations, change controls and the implementation of corrective actions.

- Oversight of internal GCP and QMS training for permanent and contract staff.

- Maintain and develop the vendor oversight process, and perform vendor audits and assessments, as applicable.

- Support the work of the company in the provision of expert clinical quality assistance to client companies, ensuring client expectations and interests are exceeded at all times.

- Research and prepare global research plans and strategies on behalf of client companies ensuring a platinum-standard approach at all times.

- Plan and manage quality requirements including timelines, budgets, personnel resources, investigational sites, vendors and key project deliverables.

- Assist wider team in the set-up, management & conduct of clinical investigation sites worldwide, ensuring that local and global GCP requirements are being followed and that Research compliance is being followed throughout.

- As required, take advantage of professional networking opportunities to promote the company and its services to appropriate parties.

- Design and deliver formal client presentations, including proposed solutions.

- Undertake continuing professional development activity to ensure awareness of current quality and regulatory standards.

- Work with management to prioritise actions.

- Any other duties, within reason and capability, as determined by company management.

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PERSON SPECIFICATION

Job Title: Head of Quality Compliance, Global Clinical Research

Criteria	*Essential*	*Desirable*
Qualifications/ Attainments	• Scientific degree or equivalent relevant industry experience • Current GCP certification	• MSc in Quality Management

Relevant Knowledge and Experience	• Proven 5+ years' experience conducting GCP sponsor and investigator audits, preparation for regulatory inspections e.g. MHRA/BIMO etc. • Proficient in QA procedures and knowledge of relevant GCP standards • Experience of leading CAPA initiatives • Successful implementation of quality plans for all types of systems/processes • Ability to review and evaluate clinical data/records • Strong QMS experience • Experience of working in a medical device GCP environment • Knowledge of regulations in key global markets as they pertain to general medical, IVDD's and/or CDx device research • Knowledge of changing regulations in the EU relating to general medical and/or IVD medical devices	• Knowledge of regulatory requirements • Knowledge of ISO 14155 and/or EN 13612 and implementation to achieve and maintain device GCP compliance
Skills and Competencies	• Demonstrated coaching/mentoring skills • Excellent interpersonal skills • Excellent communication skills, both verbal and written, including strong presentation and influencing skills • Evidence of strong analytical, problem solving and decision-making abilities • Evidence of well-developed organisational, planning and time management abilities • Proven ability to achieve results while working independently and on own initiative • Proficient in the use of word processing, spreadsheet, database, and presentation software	• Experience with EDMS and computerised audit management systems

Circumstances	• Able to work flexibly as required to ensure business needs are met • Valid full driving licence and vehicle insured for business use • Able to travel extensively as required, including European and possibly global travel • Valid passport	