CAMBRIDGE COGNITION

ADVERT

JOB TITLE: Quality & Regulatory Coordinator

Reporting to (Line Manager): Lou Ward, Quality & Regulatory Manager

Working Pattern: Full-Time – 37.5 hours per week, Monday to Friday

Work Location: Hybrid but able to commute to our HQ in Bottisham (ideally 2/3 days per week) with a requirement to attend site for audits when needed.

About Us:

We are a talented global team of around 80 people, based in the UK, Canada and USA. Backed by over 30 years of scientific discovery and validation, Cambridge Cognition offers the end-to-end platform for CNS clinical trials. Our technologies are reliable in-clinic or at home for an improved patient experience and accelerated drug development.

We aim to improve the health of people worldwide with innovative assessments and digital biomarkers that provide researchers with precise measures of patients' symptoms. We lead in CNS research and are broadening our impact across therapeutic areas.

Are you interested in working for a company whose main goal is to make a difference to the health of current and future generations, through the knowledge and experience of our passionate team?

Role Summary:

Alongside the Quality & Regulatory Manager, you will be responsible for driving quality standards across the organisation and ensuring regulatory compliance throughout the business. You will take ownership of key quality processes including maintaining the Quality Management System (QMS) and supporting audit processes.

This is a hands-on role, requiring flexibility to work on a wide variety of tasks.

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What you'll be doing:

As the Quality & Regulatory Coordinator at Cambridge Cognition, you will be:

- Implementing and maintaining quality procedures, standards, and specifications.
- Reviewing and maintaining the eQMS including all Quality documents and records
- Supporting the internal and external audit processes including conducting and hosting audits and ensuring corrective actions are applied to minimise future issues.
- Monitoring activities relating to non-conformities
- Assisting with regulatory activities and reviewing regulatory documentation.
- Monitoring regulatory intelligence
- Providing local support on all quality matters to maintain compliance across activities.
- Supporting internal teams with client requirements

What we need from you:

Essential Requirements:

- Familiarity with GxP guidelines e.g. GCP
- Proven experience in QA, ideally within the regulated life sciences or healthcare devices industry
- Demonstrable experience of working with a QMS
- Training/understanding of requirements of ISOs (9001 and/or 13485, 27001)
- Proficiency in Microsoft Office Suite (Word, Excel, PowerPoint) and document management systems.
- Understanding of internal and external auditing processes
- Strong organisation skills and attention to detail, with ability to effectively prioritise tasks to meet deadlines.
- Excellent verbal and written communication skills
- Strong relationship building and stakeholder management skills

Desirable:

- Auditor qualification
- Experience in CSA (Computer Systems Assurance
  Experience using Qualio (eQMS)

What we can do for you:

- Be part of a friendly team that are driven to achieve commercial success and have a positive impact on global health
- Flexibility
- Hybrid Working– 2/3 days a week at our office in Bottisham, just outside Cambridge; and the rest of the week can be worked at home,
- 26 days annual leave per year plus bank holidays (including 3 days for Christmas break) with a holiday buy/sell scheme
- Generous pension with up to 6.5% company contribution, (minimum 2.5% Employee Contribution)
- Life assurance 2x base salary
- Private Health Insurance - Bupa Insurance, Simply Health Cashback Scheme
- Employee assistance programme including 24/7 virtual GP
- Discretionary share options – a % of base salary, with nominal exercise price and vesting over 3 years (subject to board approval)

We're not currently able to sponsor employees. This means we're unable to consider applications from candidates who are not eligible to work in the country our roles are based.

Cambridge Cognition is an equal opportunities employer, we are committed to equality of opportunity for all employees and application from individuals are encouraged regardless of age, disability, sex, gender reassignment, sexual orientation, pregnancy and maternity, race, religion or belief, marriage, and civil partnerships.