



Frontier Science (Scotland) Ltd

Grampian View
Kincaig, Kingussie, PH21 1NA
Inverness-shire
Scotland
Tel: +44 (0)1540 651 000
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POSITION: QUALITY ASSURANCE OFFICER

Introduction

Do your interests include; **cycling, walking, climbing, water sports and/or skiing**? Would you like to live in an idyllic area of outstanding natural beauty with the opportunity to step out of your back door onto Scotland's most dramatic mountain range and all the area has to offer, and at the same time pursue a professional career and be involved in the development and analysis of clinical trials?

The opportunity we are offering provides not only the benefit of a unique lifestyle with access to all kinds of outdoor activities, but also the opportunity to work with a highly respected not-for-profit organisation which offers consultation and support to both industry and academic sponsored clinical trials. Our independent approach allows us to lead work on exciting trials ranging from small academic research projects to large international multi-centre trials seeking regulatory approval for new therapies. We have trials in a variety of disease areas including breast cancer, colonoscopy screening and neuropathic pain. We model our environment on an academic setting, but have little of the bureaucracy associated with large organisations.

As we have significant experience in all aspects of clinical trials management, staff are exposed to all aspects of trial delivery from protocol development, evolution of statistical analysis plans to the final analysis and presentation of long-term follow-up results. We are committed to comprehensive training, continuing education and professional development, and provide opportunities for staff to attend workshops and conferences.

Overview of Position

Frontier Science Scotland (FSS) are currently looking to appoint a Quality Assurance (QA) Officer to support our FSS QA programme. We have an exciting opportunity for an individual to join a small QA team working at our unique Scotland office in a relaxed, friendly and technically challenging and adaptive area of the business. This role will report to the Deputy Director who provides QA oversight. The successful candidate will be provided with all the necessary training and appropriate personal development opportunities to thrive in the role. There is currently no line-management responsibilities with this position. The role is varied in clinical trial subject area exposure, interacting with Data Management, Statistics and Programming, Trials Management and Technical Writing, IT and Business Support. This is a full time position but we are willing to consider part time candidates.

Key Responsibilities

- Day to day management of the FSS quality management system
 - Procedure, deviation and risk management
 - Review FSS policies and procedures



Registered in Scotland (SC 220936); Registered Office: Grampian View, Kincaig, Kingussie, PH21 1NA Inverness-shire,
Recognised as a Scottish Charity (SC033112).



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- Quality and compliance training
- Guidance on implementation of quality control systems
- Perform internal audits
- Assist with audit/inspection readiness and hosting
- Assist with breach and incident management
- Corrective Action Preventative Action (CAPA) tracking
- Perform external audits as directed
- Author QA procedural documents
- Maintain current knowledge of regulations and standards and provide guidance to staff
- Work closely with the Technical Writer team in the development and retention of organisational and trial master file documentation
- Collaborate with QA colleagues in other Frontier Science offices (USA and Greece)
- Provide QA advice to clinical trial project teams, including review of trial essential documents

Essential

- Educated to degree level or equivalent
- Prior QA experience in a regulated industry or academia is preferred – consideration will be given to candidates with clinical trials experience with familiarity of Good Clinical Practice (GCP) guidelines or experience working in healthcare/scientific/medical sector
- Must have a strong interest in quality and compliance
- Critical thinking and analytical skills. Ability to risk assess
- Strong writing skills with good written English
- Attention to detail and accuracy
- Excellent communication and interpersonal skills, ability to facilitate discussion
- Influencing skills
- Ability to work independently, work on multiple assignments simultaneously and adapt to changing priorities
- Collaborative approach to work, with the ability to form effective working relationships with a diverse range of people both internal and with external partners

Other Desirable Skills, Knowledge and Experience

- Monitoring or auditing experience
- Understanding and working application of current UK, EU and US regulatory requirements relating to international clinical trials, including data protection legislation
- Resourceful, pragmatic and risk based approach to quality management



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Other

Frontier Science (Scotland) Ltd (FSS) is a not-for-profit organisation run along academic lines and recognised as a Scottish Charity. FSS is involved in the management, statistical analysis and reporting for clinical trials. FSS currently has a team of 37 staff members and our office is situated in unique premises in the Highland village of Kincraig, 6 miles south of Aviemore. FSS offers 28 days paid holiday plus 8 statutory public holidays per year and offers great benefits in terms of remuneration, non-contributory pension, fitness club reimbursement, bike to work scheme, life insurance and tuition reimbursement. More details will be available at the interview.

Starting salary for this position will be competitive based on relevant prior experience. The position is probationary for 6 months and the start date is negotiable. Some travel will be required.

Closing date for applications is 07 June 2019. Applicants should submit a completed Application Form, and submit along with their current CV and a covering letter. If there are any questions or you would like to discuss the position further please contact recruitment@frontier-science.co.uk or call 01540 651 000.