Candidate Information

Position:	Technician (Quality & Material Specialist) - 0.8 FTE
School/Department:	Wellcome-Wolfson Inst for Experimental Medicine
Reference:	22/110169
Closing Date:	Monday 3 October 2022
Salary:	£29,619 per annum (pro rata)
Anticipated Interview Date:	Thursday 13 October 2022
Duration:	12 months

JOB PURPOSE:

The postholder will be based in the Evolve laboratory managed by Dr Vanessa Brown, and will manage, plan and coordinate quality control programmes to ensure processes are performed in accordance with defined protocols and regulations, and will be responsible for overseeing all sample kitting activities by close liaison with study sites.

To undertake analytical duties for the diagnostic and research activities of the Evolve Laboratory. Carrying out experimental and analytical diagnostics and investigations.

MAJOR DUTIES:

1. Responsible for managing all QA operations in adherence to GCP and regulatory requirements, including reviewing, testing and adapting existing procedures, and preparing performance reports for end to end sample processing, taking remedial action when required and as directed by senior staff.
2. Identifying and troubleshooting issues that may affect laboratory processes and other support to daily QC operations.
3. Execution of internal audits to monitor quality performance as determined by the established audit schedule and as required for cause reasons.
4. Assist in the preparation, tracking and management of external audits and regulatory and accreditation inspections. Participate in root cause investigation and preparation of CAPA plans. Follow up on corrective actions to ensure timely close out of action. Communicate quality or compliance concerns with urgency.
5. Ensure the timely and efficient provision processing and testing of a large range of human samples using various platforms and the handling of data and/or calculations and identifying issues as required.
6. Ensure maintenance of current/future stock requirements of equipment and consumables for various studies.
7. Monitor and maintain a safe working environment to ensure that Health and Safety procedures and relevant legal requirements are met. Ensure compliance and adherence to all Health and Safety procedures. Conduct monthly lab inspections, document and record findings/solutions for audit purposes.
8. Ensure that work is carried out in line with Standing Operational Procedures and local policies. Responsible for updating, developing, and implementing Local and Global Clinical Trials Standard Operating Procedures (SOPs), COSHH and Risk assessments and maintaining all relevant training and competency records (including both electronic records and hard copy files).
9. Responsible for own work and that of junior members of staff under the direction of senior scientific staff. This will include all aspects of the clinical, scientific & technical work, staff, equipment and quality systems.
10. Maintain a current understanding of GCP and ICH regulations and guidelines as they pertain to clinical trials.
11. Develop and organise a schedule for calibration, performance verification, and maintenance of all laboratory equipment and maintain all relevant records including an equipment inventory.
12. Plan, coordinate and oversee all kitting activities: responsible for operational planning, strategy, quality, and delivery of Clinical Trial Kits for distribution, meeting all deadlines.
13. Liaise with collaborators at study sites to ensure adequate stock control at sites to enable the smooth-running of the study.

14. Design and redesign (as needed) kitting procedures and associated paperwork for an effective, streamlined process with high quality.
15. Provide short- and long-term kit forecasting and build schedules for all studies, whilst also maximising utilization of kit components across multiple studies.
16. Arrange and manage ordering of equipment and consumables, monitor their use and provide detailed estimates to facilitate forward planning of maintenance costs, budgets and study costs.
17. Liaise with suppliers, including obtaining quotes, liaising with purchasing/procurement, assisting with formal tendering processes and supporting other staff members to ensure timely completion of financial records/procedures.
18. Carry out other duties, reasonably requested by line manager, which are appropriate to the post.

ESSENTIAL CRITERIA:

1. Academic and/or vocational qualifications ie OND/ONC and/or NVQ level 4 in relevant subject (or equivalent);OR Substantial relevant experience working in a multi-functional laboratory.
2. Minimum of 4 years relevant hands-on work experience to include: working in inflammation research/molecular biology/microbiology laboratory; or clinical laboratory – in a wide range of laboratory methods.
3. Minimum of 4 years relevant hands-on work experience to include: working in inflammation research/molecular biology/microbiology laboratory; or clinical laboratory – in a wide range of laboratory methods.
4. At least 2 years experience working within a quality management system/regulatory environment and in the development of CAPAs.
5. Experience of coordinating clinical sites in various laboratory aspects, specifically overseeing all kitting activities.
6. Experience of handling clinical samples.
7. Experience of working to SOPs.
8. Well-developed understanding and knowledge of relevant regulations and procedures including Health and Safety requirements, HTA and MHRA/EU regulations in relation to GCP
9. Experience of data management (eg.data entry, collation and presentation).
10. Experience with a laboratory information management system (ItemTracker).
11. An excellent communicator with the ability to communicate at all levels internally and externally, both verbally and written.
12. Ability to develop and demonstrate standard equipment and techniques.
13. Self-motivated with initiative and drive.
14. Strong attention to detail and high standards of accuracy are essential.
15. Ability to prioritise own work within a general plan to meet deadlines.
16. Ability to carry out practical laboratory tasks to a consistently high standard.
17. Ability to provide reports on project progress.
18. Ability to train staff and allocate work.
19. Analytical and problem solving skills.
20. Due to the nature of the projects, flexibility of working hours will be required.

DESIRABLE CRITERIA:

1. Degree or higher level qualification in a relevant subject.
2. Experience in delivering training to staff on Quality topics.