JOB DESCRIPTION

Job Title: Quality Assurance Manager
Department: Research Governance and Integrity Office (RGIO)
Faculty/Professional Service: Strategic Research Office
Location: Keppel Street, London
Reports to: Head of Research Governance and Integrity
Full Time/Part Time/Casual: Full time
Grade: Grade 6
Overall Purpose of the job: The purpose of the role is to ensure that clinical trials and high risk interventional research sponsored by LSHTM meet the highest standards of quality assurance practices and research governance, complying with the relevant national and international regulatory and legislative requirements, guidelines and institutional policies and procedures. The post-holder will be specifically responsible for developing, implementing and maintaining robust Quality Assurance (QA) systems and processes. They will promote a quality culture in the conduct of clinical trials at LSHTM, advising on all aspects of trial governance and quality assurance and regulatory matters. The role will lead on identifying risk proportionate factors critical to trial quality for trials, the protection of the rights, safety and well-being of participants in the UK and internationally and the embedding of policies and practices that ensure that trial results are scientifically sound, reliable and verifiable. The post holder will work closely with the LSHTM Clinical Trials Unit (CTU), principal and chief investigators, trials teams including trial managers and data managers. Within LSHTM, the post holder will ensure collaborative working with specialist colleagues in the Research Governance and Integrity Office (RGIO), the Strategic Research Office (SRO) and associated services more widely. The post holder will also work in partnership with the Human Tissue Facilitator to ensure shared QA principles and institutional consistency of approach with the overarching LSHTM Quality Management System (QMS) that covers the main regulated areas of LSHTM research. This is a new post and it presents an exciting opportunity for a motivated individual to apply their experience in a supportive environment to shape the direction of LSHTM's clinical trial quality assurance strategy and practice and the direction of the institutional QMS.

General Information

The London School of Hygiene & Tropical Medicine (LSHTM) is one of the world's leading public health universities.

Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice.

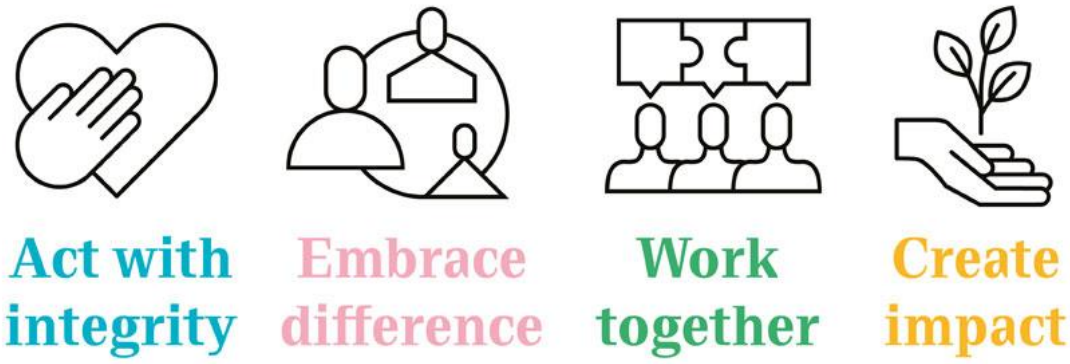
Staff and students are committed to helping create a more healthy, sustainable and equitable world for everyone, because we believe our shared future depends on our shared health.

We embrace and value the diversity of our staff and student population and seek to promote equity, diversity and inclusion as essential elements in contribution to improving health worldwide. We believe that when people feel respected and included, they can be more creative, successful, and happier at work. While we have more work to do, we are committed to building an inclusive workplace, a community that everyone feels a part of, which is safe, respectful, supportive and enables all to reach their full potential.

To find out more please visit our Introducing LSHTM page.

Our Values

Our values establish how we aspire to achieve our mission both now and in the future - demonstrating what it means to work and study at LSHTM. Please visit our LSHTM Values page for further information.



FACULTY/DEPARTMENT INFORMATION

As part of the wider Strategic Research Office, the Research Governance and Integrity Office (RGIO) supports and promotes high quality research, with the development and implementation of best practice across research ethics, research governance and research integrity for all research conducted by staff and students at LSHTM.

The Research Governance and Integrity Office consists of the Head of Research Governance and Integrity, a Research Facilitator specialising in clinical trials and NHS research, an Ethics Facilitator and a Human Tissue Facilitator.

Main Duties and Responsibilities

- Develop, implement and maintain LSHTM's Quality Assurance systems for clinical research, ensuring full alignment with regulations, key international standards and institutional policies, processes and approaches in collaboration with London based teams and those in LSHTM's overseas units (the Gambia and Uganda).
- To collaborate with the RGIO team to ensure that LSHTM SOPs are in place, monitored, updated and appropriately communicated.
- Work with trial teams and CTU staff to develop appropriate quality by design approaches and plans, ensuring that all quality-related matters are effectively managed and documented in a risk-proportionate manner to support the integrity and reliability of results
- Identify areas for improvement of trial processes and collaborate with internal and external stakeholders to ensure the implementation of resulting quality enhancements.
- Oversee and approve sponsor and trial level risk assessments to establish risk-proportionate approaches to trial conduct, monitoring and oversight.
- Maintain a risk based institutional programme of internal audits of LSHTM sponsored trials, including, conducting or commissioning audits, writing or reviewing reports, approving corrective/ preventative actions (CAPA) and follow-up of CAPA implementation.
- Undertake occasional site auditing visits, including to overseas sites where necessary.
- Ensure an oversight of trial quality control practices and oversight activities, including advising trial teams with regards to trial-specific monitoring requirements and reviewing trial monitoring plans.
- Support the assessment of the resource requirements of monitoring activities, including trial-specific monitoring FTE estimates and associated costs for grant/funding applications.
- Compile remote monitoring activity reports for LSHTM management, trial sponsors and CTU Senior Management, as applicable.
- Prepare site reports and advise trial staff about the findings of audits required actions. Escalate concerns appropriately.
- Manage the periodic review of CTU Working Practice Documents (WPDs), identifying gaps and determining when WPDs are no longer required.
- Prepare Quality Assurance (QA) training materials and deliver induction training for new staff, and refresher training on relevant LSHTM Standard Operating Procedures (SOPs) and WPDs.
- Maintain an expert understanding of regulations governing the conduct of trials in the UK and internationally, including ICH Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), The UK Policy Framework for Health and Social Care Research (2017) and the UK clinical trials regulations
- Proactively assess the impact of new and emerging regulations on existing procedures, policies and documents, cascading the implications of changes within the organisation.
- Assist trials staff in identifying, managing and reporting serious breaches.
- Assist, guide and support CTU staff in preparing for external audits and acts as host for statutory inspections by Regulatory Authorities.

- Represent LSHTM at UK Clinical Research Collaboration (UKCRC) QA meetings.
- Contribute to teaching and services organized by the CTU to the wider LSHTM community in line with the post-holder's expertise.

Generic duties and responsibilities of all LSHTM employees

This job description reflects the present requirements of the post but may be altered at any time in the future as duties and responsibilities change and/or develop providing there is consultation with the post-holder.

The post-holder will carry out any other duties, tasks or responsibilities as reasonably requested by the line manager, Dean of Faculty, Head of Department or Head of Professional Service.

The post holder will be responsible and accountable for ensuring all LSHTM policies, procedures, regulations and employment legislative requirements are adhered to including equality and diversity and health and safety.

This job description is not a definitive or exhaustive list of responsibilities but identifies the key responsibilities and tasks of the post holder. The specific objectives of the post holder will be subject to review as part of the individual Performance and Development Review (PDR).

PERSON SPECIFICATION

This form lists the essential and desirable requirements needed by the post holder to be able to perform the job effectively.

Applicants will be shortlisted solely on the extent to which they meet these requirements.

Competency	Evidence	E / D
Education, Qualifications and Training	• A relevant undergraduate degree or equivalent professional qualification and/or demonstrable experience. • A professional qualification in Quality Assurance in clinical trials or trial management.	E D
Experience	• Extensive experience working in a regulated QA environment leading continuous process improvement in the health or pharmaceutical sector • Considerable experience in the conduct of UK and international clinical trials, including those involving Investigational Medicinal Products. • Significant experience of conducting and/or senior involvement in internal audits and monitoring visits and developing audit and monitoring plans. • Experience of hosting Medicines and Healthcare Regulatory Agency (MHRA) audits and/or GCP inspections by regulatory bodies. • Experience in working to, writing and reviewing Standard Operating Procedures.	E E E E E
Knowledge	• Comprehensive knowledge of relevant legislative and policy issues, including: Medicines for Human Use (clinical trials) Regulations (2004) , Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024, the Human Tissue Act (2006), UK Data Protection Act (2018), ICH Good Clinical Practice, HRA UK Policy Framework for Health and Social Care Research and the Declaration of Helsinki • Knowledge and understanding of standards and legislation that govern research in the NHS. • An understanding and appreciation of the implications of conducting clinical trials in vulnerable populations and resource-limited settings	E E D

General	• Ability to listen to others and use critical and tactful questioning techniques to identify core issues to negotiate a path forward that meet the needs of all stakeholders.	E
	• Excellent written and oral communication skills and the ability to apply these to create technical documents (e.g. regulatory reports, Standard Operating Procedures) and to communicate with research staff at all levels	E
	• Ability to work independently of trials teams while garnering respect and cooperation from colleagues in the UK and internationally.	E
	• Ability and interest in delivering specialised teaching and training in quality management in clinical research.	E
	• A commitment to working in equitable partnerships with collaborators in the UK and internationally.	E

E-Essential: Requirement without which the job could not be done
D-Desirable: Requirements that would enable the candidate to perform the job well

Date compiled: August 2026

Salary and Conditions of Appointment

The post is fixed term for 3 years and full-time 35 hours per week, 1.0 FTE. The salary will be on the LSHTM salary scale, Grade 6 in the range £45,728 - £51,872 per annum (inclusive of London Weighting)

The post will be subject to the LSHTM terms and conditions of service. Annual leave entitlement is 30 working days per year, pro rata for part time staff. In addition to this there are discretionary "Wellbeing Days." Membership of the Pension Scheme is available.

LSHTM operates a Hybrid Working Framework which, alongside agreed service requirements, enables teams to work more flexibly where the role allows - promoting wellbeing and a better work/life balance. Please note that roles based in London are required to work on-site a minimum of two days per week.

Application Process

Applications should be made on-line via our jobs website. Applications should also include the names and email contacts of 2 referees who can be contacted immediately if appointed. Online applications will be accepted by the automated system until 10pm of the closing date. We regret that late applications cannot be accepted. Any queries regarding the application process may be addressed to jobs@lshtm.ac.uk.

The supporting statement section should set out how your qualifications, experience and training meet each of the selection criteria. Please provide one or more paragraphs addressing each criterion. The supporting statement is an essential part of the selection process and thus a failure to provide this information will mean that the application will not be considered. An answer to any of the criteria such as "Please see attached CV", "Yes" or "No" will not be considered acceptable and will not be scored.

Please note that if you are shortlisted and are unable to attend on the interview date it may not be possible to offer you an alternative date.

Asylum and Immigration Statement

LSHTM will comply with current UKVI legislation, which requires all employees to provide documentary evidence of their legal right to work in this country prior to commencing employment. Candidates will be required to email a copy of their passport (and visa if applicable) to HR prior to their interview and if appointed will be asked to bring the original documents in to be copied and verified before their start date.

Applications from candidates who require sponsorship to work in the UK will be considered alongside other applications. Applicants who do not currently have the right to work in the UK will have to satisfy UK Visas & Immigration regulations before they can be appointed.

Further information about Sponsorship and eligibility to work in the UK, can be found on the government immigration rules page.