LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE
FACULTY OF INFECTIOUS AND TROPICAL DISEASES
DEPARTMENT OF CLINICAL RESEARCH

EBOVAC Quality Manager

GENERAL INFORMATION

The London School of Hygiene & Tropical Medicine

The London School of Hygiene & Tropical Medicine is a world-leading centre for research and postgraduate education in public and global health. 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.

Founded in 1899, the School has expanded in recent years at its two main sites on Keppel Street and Tavistock Place. Our staff, students and alumni work in more than 150 countries in government, academia, international agencies and health services. Research income has grown to more than £110 million per year from national and international funding sources including UK government and research councils, the European Union, the Wellcome Trust, Gates Foundation and other philanthropic sources. The School’s multidisciplinary expertise includes clinicians, epidemiologists, statisticians, social scientists, molecular biologists and immunologists, and we work with partners worldwide to support the development of teaching and research capacity.

Our education provision has expanded to more than 1,000 London-based Master’s and Research students, 3,000 studying postgraduate courses by distance learning, and 1,000 each year on short courses and continuous professional development. Our free online courses (Moocs) are studied by more than 30,000 participants globally.

The School performs well in various global university league tables. In the US News Best Global Universities Ranking 2017, we are ranked sixth in the world (together with Oxford University) in the fields of social sciences and public health. In the 2016 CWTS Leiden Ranking, the School was ranked fifth in the world for research impact across all disciplines, based on the share of institutions’ outputs within the top 1% of papers by citation in all areas of science and independent of size of output.

The School was named University of the Year 2016 by Times Higher Education, in recognition of our response to the Ebola epidemic. The School is a member of the M8 Alliance of Academic Health Centers, Universities and National Academies, the Association of Schools of Public Health in the European Region, and the Consortium of Universities for Global Health.

Faculty of Infectious and Tropical Diseases

The Faculty of Infectious and Tropical Diseases encompasses all of the laboratory-based research in the School as well as that on the clinical and epidemiological aspects of infectious and tropical diseases. It is headed by Brendan Wren, who is Professor of Microbial Pathogenesis. The range of disciplines represented in the faculty is very broad and inter-disciplinary research is a feature of much of our activity. The spectrum of diseases studied is wide and there are major research groups with a focus on malaria, tuberculosis, HIV/AIDS and other sexually transmitted diseases, vaccine development and evaluation, and vector biology and disease control. The Faculty is organised into four large research departments comprising: Pathogen Molecular Biology, Immunology and Infection, Disease Control, and Clinical Research. There is close interaction between scientists in different research teams. The Faculty has strong overseas links, which
provide a basis for field studies and international collaborations in developed and developing countries. The teaching programme includes MSc courses, taught in-house and by distance learning, which are modular in structure, a variety of short-courses and an active doctoral programme (PhD and DrPH). For further information on the Faculty see: http://www.lshtm.ac.uk/itd/index.html.

**Department of Clinical Research (Head: Professor David Mabey)**
The Department of Clinical Research addresses infectious diseases of major public health importance in developing countries. Activities include trials of new therapies, vaccines and educational interventions; the development of new diagnostic tests; studies to elucidate the immunological and molecular correlates of pathogenesis and protective immunity, and to identify genetic polymorphisms conferring protection or susceptibility to infectious diseases; health services research which aims to identify the most efficient and cost-effective way to deliver health care; and health policy analysis. In addition to our many overseas collaborations, we have close links with the Hospital for Tropical Diseases, in purpose-built accommodation on the main UCL Hospital campus, five minutes’ walk from the School. The Wellcome Trust Bloomsbury Centre for Global Health Research is based in the Department, and supports Clinical Fellows at all levels, most of whom are based overseas.

The Department’s main research interests include HIV and related infections; in particular, the interaction between HIV infection and tuberculosis, and other sexually transmitted diseases; malaria; trachoma; leprosy; diagnostic tests for resource limited settings; eye health; disability; and travel medicine.

**Department of Disease Control (Head: Professor James Logan)**
This multidisciplinary Department includes epidemiologists, entomologists, anthropologists and social scientists, clinical scientists, public health engineers and geographers. This range of expertise provides us with a battery of tools for focusing on the control of diseases that are insect-borne, water-borne or associated with poor hygiene – mostly in developing countries. Much of the research can be categorised as: evaluating disease control interventions; investigating implementation strategies - including working with the private sector; understanding the factors underlying household behaviour in relation to family health; or determining how control resources can be targeted most efficiently. Particular attention is paid to research directed at current health policy issues, including the gap between policy and practice.

The Department's Environmental Health Group plays a leadership role in research and operational support for hygiene behaviour change, household water supply and sanitation. Three key programmes which contribute to the work of the Group are the DFID funded consortium Sanitation and Hygiene Applied Research for Equity (SHARE), the Hygiene Centre (Unilever) and the improved sanitation randomised, controlled field trial jointly funded by the Bill & Melinda Gates Foundation and International Initiative for Impact Evaluation (3ie).

The Department houses the largest research group in LSHTM working on malaria control. Ongoing projects include: research capacity strengthening in Africa through the work of the Malaria Capacity Development Consortium (MCDC); novel approaches to combating malaria in pregnancy (MiP) in both Africa and India; a number of projects which develop and evaluate delivery mechanisms to improve ACT access, targeting, safety and quality, all funded by the ACT Consortium. In addition, staff are involved in studies of Seasonal Malaria Chemoprevention (SMC) in West Africa and are supporting work on the large Phase 3 clinical trial study of the RTS,S malaria vaccine in children.

The Department is world-leading in applied entomology and insect borne diseases, and has provided a testing service for control products for over 20 years. The Arthropod Control Product Test Centre Arctec provides access to the Department’s valuable mosquito colonies and in-house facilities for testing of repellents, insecticides and after-bite treatments. Its entomological field sites in Tanzania, Benin, The Gambia and Kenya are involved in a variety of vector borne disease control trials. The PAMVERC alliance between LSHTM and African partners work in partnership
with WHO and the manufacturing industry on product development and evaluation under laboratory and semi-field conditions and in community trials.

Staff from the Department lead on studies investigating how meningococcal meningitis is spread in Africa and the impact of a new serogroup meningococcal A vaccine on reducing transmission (MenAfriCar Consortium). Staff are also assisting in the evaluation of the impact of introduction of a pneumococcal conjugate vaccine into the routine EPI programme of The Gambia and in the initial testing of a new pneumococcal protein vaccine in the same area.

Also based with the Department is the IDEAS (Informed Decisions for Actions) project, which aims to improve the health and survival of mothers and babies through generating evidence to inform policy and practice. The Department also includes a major grouping of researchers using spatial analysis in public health.

**Department of Immunology and Infection (Head: Professor Greg Bancroft)**

Research in the Department of Immunology and Infection centres on analysis of the host response to infection at the molecular, cellular and population levels. The goals are to develop a greater understanding of basic mechanisms of immunological protection versus pathology, and to apply this knowledge to the development of immunological interventions and the identification of correlates of immune status. Our work involves application of state-of-the-art cellular and molecular approaches to the in vitro analysis of pathogen-host cell interactions, to in vivo studies in models and to the study of immunity at the population level in disease endemic areas. Main areas of research include the regulation of acute and chronic inflammation; macrophage-pathogen interactions; cellular pharmacology; the production of cytokines during innate and acquired immune responses; T-cell function and antigen recognition; the mechanisms of immunopathology; the development of vaccines; and delivery systems for vaccines and drugs.

Current research includes the role of acute phase proteins in resistance to infection, homeostasis and inflammatory disease, mechanisms of macrophage activation, control of cytokine synthesis and mammalian lectin interactions (J. Raynes); intracellular trafficking and secretory pathways of cells of the immune system (T. Ward); the role of innate responses in resistance to the bacterial pathogens, *Mycobacterium tuberculosis* and *Burkholderia pseudomallei*, activity and regulation of natural killer cells and their effect on macrophage activation and recruitment, regulation of chemokine receptors during infection and granulomatous tissue responses in the lung against *Cryptococcus neoformans* and *Mycobacterium tuberculosis* (G. Bancroft); longitudinal studies on immune correlates of protection against malaria in Uganda and a cluster-randomized trial on the impact of targeted interventions on malaria transmission in Kenya and Mali (T. Bousema); identification and evaluation of novel drugs and formulations for the treatment of leishmaniasis, malaria, human African trypanosomiasis (sleeping sickness) and American trypanosomiasis (Chagas disease). This research includes projects on miltefosine, AmBisome and topical paromomycin as well as on drug – immune response interactions and PK PD relationships (S Croft); correlates of protection against tuberculosis and studies of BCG vaccination, human CD8+ T-cell responses to mycobacterial antigens and synthetic peptides, use of whole blood assays in immuno-epidemiology (H. Dockrell); innate and adaptive immunity to malaria including activation of natural killer cells, cytokine regulation in clinical immunity and immunopathology, regulation of antibody production and immunoglobulin class switching (E. Riley); induction and regulation of innate and adaptive immune responses to malaria pre-erythrocytic stage and blood stage parasites (J. Hafalla); using anti-malarial antibodies as a marker of malaria exposure & assessment of the use of sero-epidemiology to monitor and target malaria control measures www.seromap.com (C. Drakeley) transmission of *Plasmodium falciparum* malaria including antibody responses to gametocyte-infected erythrocyte surface antigens, effect of gamete antigen variability on transmission, gametocyte sequestration and development and gametocyticidal drug therapy (C. Sutherland); drug discovery for helminthic diseases notably schistosomiasis (Q. Bickle); impact of concomitant viral, bacterial, protozoal and helminth infections on induction of immune responses and immunopathology and T cell regulation and induction of mucosal immune responses during intestinal nematode infections (H. Helmy); anti/protozoal chemotherapy with focus on anti-leishmanial drug discovery and development including drug combinations and drug delivery
systems, anti-leishmanial vaccine development and immunotherapies, models for drug and vaccine development and the role of macrophages in context of anti-leishmanial drug treatment (K Seifert); the identification and evaluation of novel drugs and drug delivery systems for leishmaniasis, trypanosomiasis and malaria, interaction between antiprotozoal drugs and the immune response (V. Yardley).

Host response to vaccination and development of improved vaccine strategies for protection against tuberculosis, growth inhibition assays, T-cell responses and vaccine trial immune monitoring (H. Fletcher) Dissecting red blood cell invasion pathways in the malaria parasite Plasmodium knowlesi (R. Moon)

**Department of Pathogen Molecular Biology (Head: Professor David Conway)**

Research in the Department of Pathogen Molecular Biology focuses on the molecular biology and genetics of pathogens and interaction with their hosts, to improve understanding and control of infectious diseases. This includes: (i) determining mechanisms of infection of globally important viral, bacterial and parasitic pathogens; (ii) deciphering the genetic diversity of disease agents in natural populations to understand epidemiological and functional processes, (iii) studying immune evasion mechanisms of particular disease agents, (iv) exploiting pathogens as model biological systems, and (v) developing practical applications including improved diagnostic tests and characterisation of vaccine candidates or drug targets.

Studies in the Department include analyses of malaria parasites (*Plasmodium* spp), Chagas disease (*Trypanosoma cruzi*), African sleeping sickness (*Trypanosoma brucei*), amoebic dysentery (*Entamoeba*), the Leishmania species, bacterial food borne pathogens (*Campylobacter jejuni* and *Yersinia enterocolitica*), gastric ulcers/cancer (*Helicobacter pylori*), pseudomembranous colitis (*Clostridium difficile*), plague (*Yersinia pestis*), paddy field melioidosis (*Burkholderia pseudomallei*), Tuberculosis (*Mycobacterium tuberculosis*), Pneumonia (*Streptococcus pneumoniae*), Bluetongue viral disease of livestock, Herpesviridae, SARS, hemorrhagic fever viruses, and enteric rotaviruses that cause significant diarrhoeal disease.

The overall aim of our research is to understand the complex and dynamic ways by which pathogens modulate virulence and interact with the human host. Such a holistic approach will vastly increase the scope for the rational of design of long-term intervention strategies to reduce the burden of infectious disease. In recent years such a mission has been significantly enhanced by the availability of whole genome sequences. Members of the Department are involved in several pathogen genome projects, and post genome studies which facilitate understanding of complex parasites. The interpretation and exploitation of this basic information is the platform for numerous new avenues of research on pathogenesis, epidemiology and the evolution of virulence.

**Teaching**

The School offers 19 one year full-time taught courses leading to the Master of Science (MSc) degree of the University of London and the Diploma of the London School of Hygiene and Tropical Medicine (DLSHTM). The Faculty of Infectious and Tropical Diseases runs or contributes substantially to ten of these courses and the "Immunology of Infectious Diseases" course is run from within the Department of Immunology and Infection. In addition, the Faculty is responsible for the three-month Diploma in Tropical Medicine and Hygiene (DTM&H), the Diploma in Tropical Nursing and offers a range of specialist short courses lasting usually one or two weeks. Five MSc courses are also offered by Distance-based Learning, including one on Infectious Diseases.

**Research Training**

The School offers two doctoral training programmes. The MPhil/PhD degrees are designed for those who wish to go on to a full time research career. The DrPH is directed towards those who expect their careers to be more in the practice of public health.
EBOVAC Project

The Ebola vaccine projects – EBOVAC1, EBOVAC2, EBODAC and EBOMAN – are a series of trials and associated projects which aim to assess a novel prime-boost preventive vaccine regimen against Ebola Virus Disease (EVD). In a prime-boost vaccine regimen, individuals are first given a dose to prime the immune system, and then a boost dose, which is intended to enhance the immune response and increase the duration of the response. The vaccine has been developed by Janssen Vaccines and Prevention B.V. and the trial is funded by the Innovative Medicines Initiative (IMI, a partnership between the EU and the European pharmaceutical industry).

In addition, the EBOVAC project in Sierra Leone includes the PREVAC vaccine study. PREVAC is a large, randomized, placebo-controlled Phase II clinical trial to assess the safety and ability of three different Ebola vaccine strategies to stimulate an immune response that may protect against Ebola virus disease. The LSHTM team in Kambia district will also include a PREVAC Operations Manager position and the two operations managers will work closely with each other. The project stores, laboratory and vaccine depot will be shared between the two studies.
JOB DESCRIPTION

Post: EBOVAC Quality Manager

Department /Division/Unit: CRD

Faculty/Professional Service: ITD

Location: London, with frequent travel to project sites

FTE: Full-time 1.0

Responsible to: Deborah Watson-Jones (project PI)

Grade: PSP 6

Principal Responsibilities:

- Develop, implement and oversee the EBOVAC quality system to provide assurance that the clinical sites work in accordance with Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP), local regulations, clinical trial protocol and trial standard operating procedures.

Main Duties:

Communications

- Convey quality system principles clearly to the trial sites’ quality officers to support their training programme;
- Explain quality elements and activities to the trial site teams to ensure GCP compliance;
- Effectively communicate findings of internal quality audits to ensure their timely completion;
- Regular reporting to Principle Investigator (PI) and Trial Manager.

Teamwork and Motivation

- Act as the main point of contact for quality related issues at trial sites in Sierra Leone and Tanzania;
- Provide training and oversight of the sites’ quality officers to ensure that the quality system and procedures are established and maintained across the clinical trial activities;
- Provide training and oversight of the laboratories’ quality systems to allow them to meet GCLP accreditation standards;
- Promote quality awareness through training, mentorship and participation in forums.

Liaison and Networking

- Develop collaborative, cross-functional relationships with the trial site teams and stakeholders to facilitate compliance;
- Work with the Contract Research Organisation (CRO) and/or Sponsor to resolve any quality related issues;
- Lead quality meetings with relevant stakeholders and/or provide updates to disseminate quality related information;
- Where applicable, provide input into the creation of a quality contract or agreement to provide assurance that there is appropriate delineation of responsibilities.
Service Delivery

- Act as subject matter expert for quality related issues and provide timely support to any trial site request;
- Assist in the development and periodic review of the trial policies and procedures to ensure that the activities provided are GCP compliant;
- Where applicable, perform an independent assessment of investigation as a response to a complaint or negative feedback that is received as part of the trial’s activities.

Decision Making

- Provide advice related to decisions on trial’s quality systems as a whole;
- Support and, where necessary, approve a quality officer’s decisions related to the quality system activities.

Planning and Organisation

- Plan the quality system for the trial sites in coordination with the local quality officer;
- Support the implementation and continuous oversight of the document management system at the trial sites to provide assurance that all policies/procedures/guidelines/forms/attachments are current and appropriately controlled;
- Track and follow-up audit findings and audit files as appropriate;
- Participate in the development of training programmes and offer periodic training and refresher training related to the quality system (e.g. GCP).

Initiative and Problem Solving

- Develop and perform an internal audit programme using a risk-based approach to ensure that the study is conducted in accordance with the study protocol, GCP, GCLP, local regulations and trial procedures;
- Participate in the solution of GCP compliance issues with relevant departments;
- Lead or assist activities related to a departure from process (deviation);
- Support with the development of a CAPA system to identify, assess, implement and monitor solutions to address both actual deviations and any potential deviations from processes.

Analysis and Research

- Perform periodic quality control activities on clinical trial documentation, for example source documents, reports and maintenance of the Investigator Site File, to assess GCP compliance;
- Create key performance indicators as part of the analysis of the quality system.

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 full 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 Director of Professional Service.

The post holder will be responsible and accountable for ensuring all School 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 review (appraisal) process.
PERSON SPECIFICATION

Essential and desirable qualifications and skills for this post are as follows.

**Essential**

- Higher education to degree level, or equivalent, in a biological subject or related field.
- Experience developing, implementing and maintaining:
  - quality management systems;
  - audit programmes;
  - document management systems; and
  - deviation management (including CAPA) systems.
- Experience establishing a training programme within a GxP (good practice) environment.
- Experience of working in a developing country.
- Experience managing change in support of corporate and local objectives.
- Experience introducing policies, procedures, processes and systems effectively.
- Experience leading meetings, including devising agendas and writing minutes.
- Knowledge of data protection requirements
- Ability to organise, priorities and plan own work with minimal supervision.
- Strong verbal communication skills to work with various stakeholders.
- Excellent written communication skills.
- Ability to take initiative and to adapt to change when necessary and in the interests of the study.
- Ability to mentor and coach colleagues on the elements of a quality study.

**Desirable**

- Evidence of continuing professional development, including regular attendance on internal or external training courses.
- Extensive knowledge and application of the principles of GCP and GCLP
- Knowledge of recent and proposed changes to GCP legislation and guidelines.
- Experience leading a clinical trial laboratory to GCLP accreditation with an independent assessor.
- Experience of developing and implementing SOPs within a research/higher education environment, NGO or small-to medium organisation.

**SALARY AND CONDITIONS OF APPOINTMENT**

The post is full-time, available immediately until 30 November 2019. Salary is on the Professional Support Pathway Scale Grade 6 with a starting salary in the range of £39,304 to £44,634 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 “Director’s Days”. Membership of the Pension Scheme is available. A package of overseas allowances is available depending on whether the successful candidate would need to relocate to take up this position.
ASYLUM AND IMMIGRATION

The School will comply with the Immigration, Asylum and Nationality Act 2006, 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.

This role does not meet the minimum requirements set by UK Visas and Immigration to enable sponsorship of migrant workers. Therefore we cannot progress applications from candidates who require sponsorship to work in the UK.

Further information about Certificate of Sponsorship and eligibility to work in the UK, can be found at: www.ukba.homeoffice.gov.uk/employers/points