UNIVERSITY OF CAMBRIDGE

FURTHER PARTICULARS

The University of Cambridge

The University of Cambridge is one of the world's leading Universities, with an outstanding reputation for academic achievement and research.

Cambridge comprises 31 Colleges and more than 150 departments, faculties, schools and other institutions plus a central administration.

The Eastern Sequencing and Informatics Hub (EASIH) is a new Clinical School Research Facility hosted by the University Department of Medical Genetics. The EASIH will be involved in world class sequencing and bioinformatic research partnerships with clients both within Cambridge University and across the UK, working on matters of national and international importance in the life sciences and routine medical diagnostics. As one of four national facilities which are being funded by partnerships between the MRC and host institutions, the EASIH's aim is to provide a comprehensive and expert Next Generation Sequencing (NGS) service.

Post	Quality Manager
Summary of Role	The Quality Manager will ensure that all the facility's business (laboratory, bioinformatic and administrative functions) are conducted in adherence to ISO 9001 and ISO 17025 for the laboratory, with a view to achieving certification/accreditation in the near future. The long term goal is to achieve clinical pathology accreditation (CPA) for which the Quality manager will be responsible.
Location	EASIH, Addenbrooke's Hospital
Salary	£27,183 - £35,469
Grade	7
Closing date for applications	20 July 2012
Expected date for interview/selection	
How to apply	Completed applications consisting of a CHRIS6 (parts 1 and 3) downloadable from http://www.admin.cam.ac.uk/offices/hr/forms/chris6/ and a CV should be emailed to Lynda Smith, Departmental Administrator, (lms28@cam.ac.uk). Please quote the job reference number (SS0237) on all correspondence.

Equal Opportunities Information

The University of Cambridge appoints solely on merit. No applicant for an appointment in the University, or member of staff once appointed, will be treated less favourably than another on the grounds of sex (including gender reassignment), marital or parental status, race, ethnic or national origin, colour, disability (including HIV status), sexual orientation, religion, age or socio-economic factors.

Information if you have a Disability

The University welcomes applications from individuals with disabilities. Our recruitment and selection procedures follow best practice and comply with disability legislation.

The University is committed to ensuring that applicants with disabilities receive fair treatment throughout the recruitment process. Adjustments will be made, wherever reasonable to do so, to enable applicants to compete to the best of their ability and, if successful, to assist them during their employment.

We encourage applicants to declare their disabilities in order that any special arrangements, particularly for the selection process, can be accommodated. Applicants or employees can declare a disability at any time.

Applicants wishing to discuss with or inform the University of any special arrangements connected with their disability can, at any point in the recruitment process, contact, Lynda Smith, who is responsible for recruitment to this position, on 01223 746714, by email on lms28@cam.ac.ukor by post to Academic lab of Medical Genetics, Box 238, Addenbrooke's Hospital, Cambridge CB2 0QQ.

For additional guidance and information, applicants can contact the University's Disability Resource Centre either by telephone on 01223 332301, by email on ucam-disability@lists.cam.ac.uk or by post to DRC, Keynes House, Trumpington Street, Cambridge CB4 1QA.

Further Information

There is a range of information which you may find helpful on the University's website: www.cam.ac.uk/jobs/. This includes applying for posts, working at the University, living in Cambridge and details of current vacancies.

Role Purpose

The post holder will support the EASIH management team. They will co-ordinate the activities required to maintain and develop systems for assuring the quality of facilities, procedures, processes and data to the highest standards. The post-holder will be responsible for maintaining the legal and regulatory compliance of research/service pipelines. In addition the Quality Manager will be responsible for overseeing the validation of procedures, conduct an independent auditing programme, identify areas of regulatory risk and bring these to the attention of the EASIH management team.

The post holder will be responsible for the quality management system (QMS) and for the quality manual. The post-holder will provide guidance and advice to staff on all aspects of compliance and produce remedial action plans as necessary. They will also hold ultimate responsibility for achieving ISO 9001 certification across the whole of EASIH and accreditation to ISO 17025 for the laboratory, with a long term goal of achieving Clinical Pathology Accreditation (CPA).

Main Responsibilities

	Key duties and responsibilities	**% time spent/ frequency**
1		
	The post-holder will develop, implement and maintain a robust quality management system using their professional knowledge of quality management and an under pinning knowledge of laboratory practice to implement and maintain a Quality Management System (QMS) across EASIH that meets the requirement of ISO 9001, ISO17025 and eventually CPA(UK) and University policies and procedures.	20%
2		
	Maintain, develop and control the document management system within QPulse of all standard operating procedures for EASIH. Report to the EASIH management team on the functioning and effectiveness of the QMS.	20%
3		
	Schedule, conduct and report back on internal audits of facilities and processes to the EASIH management team, EASIH Management Committee and Head of Department/Administrator. Co-ordinate, in conjunction with external agencies, inspections and audits of the facility. Follow up external audit and verify the completion of corrective actions as required by the reports of the auditors.	20%
4		
	Ensure all adverse comments following audits and reviews are addressed by liaising with the appropriate manager and perform repeat inspections prior to QM sign-off.	15%
5		
	Educate, train and motivate staff in quality principles and practices to meet service requirements. Coordinate appropriate training (e.g. GCP, GLP) for EASIH staff and ensure individual training logs are maintained by regular review.	10%
6		
	Monitor the requirements of service users and ensure that they are reflected within the defined quality performance measures.	5%

7		
	Initiate and coordinate quality improvement initiatives as a result of new or amendments of statutory guidance.	5%
8		
	Provide regular reporting of Quality systems to the EASIH management team and the EASIH Management Committee. Ensure self-awareness of the current “state of the art” in Quality Management systems.	5%

Person Profile

Essential knowledge, skills and experience required for the role

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Education & qualifications	Degree level or equivalent in a Life Science related subject area Formal Quality Assurance Training or Qualification Post-graduate qualification desirable
Specialist knowledge & skills	Minimum of 5 years working in a regulated environment Experience of inspection and audit Management and control of documentation Experience of GCP and GLP Excellent computer skills Experience of CPA desirable Knowledge of QPulse desirable
Interpersonal & communication skills	Strong communication skills are required
Relevant experience	See specialist knowledge & skills above
Additional requirements	