

Job Description

Job Title: Biochemistry Quality Manager

Location: HSL Blood Sciences Laboratory, 1 Mabledon Place & Whitfield St

Reporting to HSL Principal Quality Manager

Accountable to: Director of Quality and Core Laboratory / Rapid Response Site Lead

Overall Job Purpose:

To support the Quality Management Group (QMG) in the administration, monitoring & implementation of the Quality Management System (QMS) across HSL Group. To oversee Quality & Compliance related activities and ensure they are carried out as a minimum requirement, in accordance with appropriate accreditation or regulatory bodies (e.g. CPA, UKAS, CQC, MHRA, GXP etc.) within the Blood Sciences laboratories at Whitfield Street and Mabledon Place, London (including any related satellite facilities)

Main Duties:

To include, but not be restricted to, the following duties:

1. To be responsible for retaining, maintaining and continuously improving, the QMS in the Biochemistry section.
2. To maintain and implement the Quality Policy for the HSL laboratory as directed.
3. To be responsible for the timely review and application of the Quality processes and documentation in Biochemistry.
4. To organise and contribute to the QMG meetings.
5. To organise and contribute towards the timely and effective running of the Management Reviews held routinely across the Group.
6. To assist with the identification and establishment of quality objectives and Quality Indicators, including formulating a plan for achieving these against appropriate and relevant timescales..
7. To assist in maintaining and further developing systems to facilitate the Continuous Improvement activities across the HSL Group.
8. To be responsible for the planning, organising and execution of an effective audit schedule for the department, with support for other Group aligned departments where necessary. To be responsible for the preparation, administration, dissemination and routine review of the quality manual.

9. To ensure compliance and maintenance of document control system for the Blood Sciences laboratory at Mabledon Place sites and Whitfield Street.
10. To ensure prompt response to enquiries and any follow up, including incidents, investigations and complaints. To ensure timely preparation of any summary and investigation reports, in accordance with the requirements of HSL QMG and compliance services.
11. To support and participate in the training of departmental staff in all Quality related activities.
12. To contribute towards and participate in the ongoing evaluation and improvement processes for the HSL laboratories.
13. To engage in activities associated with measuring and monitoring performance of the HSL laboratories.
14. To assist and support the harmonisation of processes and procedures (both quality & operational) for the department across sites within the HSL laboratories.
15. To ensure all quality related processes are performed in accordance with the relevant Health and Safety procedures.
16. As required, to provide support to other HSL Rapid Response Laboratories and Core Laboratory.
17. To monitor levels of compliance in areas of responsibility in order to identify actual and or potential risk that may require escalation and take appropriate action

General Duties

To become familiar with the day to day organisation of the department as it affects your work. You should be aware of the functions of the members of staff in the department as they affect your work. To attend laboratory meetings as required.

To undertake such work as you are assigned in a careful and efficient way and in compliance with current accreditation standards, regulatory requirements and the HSL Quality Management System.

To communicate in a friendly, helpful and non-prejudicial manner in your dealings with staff, clients and / or customers as you will be regarded as a representative of your department as well as the Company, and you should behave accordingly. Matters regarding patients are confidential and must not be discussed except in the course of your duties. You will be expected to sign an undertaking to observe all patient and Company confidentiality.

To be aware of and abide by the rules and codes of the department. This is particularly important in the case of Health and Safety and Fire procedures. To behave in a professional manner and cooperate with all other members of staff at all times.

You will be trained for the work you are expected to do. Do not attempt any work unless you are confident that you can carry it out properly.

To adhere to and to positively promote the Sonic / HSL Core Values.

To maintain high standards of work within your department.

Other duties as assigned by the Director of Quality and the HSL Principal Quality Manager.

To participate in an Annual Joint Review.

EDUCATION AND TRAINING

1. To maintain own personal development and attend departmental meetings as required.
2. To maintain registration with Health and Care professions Council (HCPC), and or relevant professional qualification institutes where appropriate, and to participate in recognised CPD activities in order to maintain these registrations.
3. To take an active interest in and keep abreast of developments in quality standards and regulations.
4. To provide support and training to the department and colleagues

ANNUAL JOINT REVIEW

Your performance will be continually assessed for competence, development and training needs and formally reviewed annually at a Training and Development Review. This will allow you to contribute to the corporate objectives of the department and HSL.

HEALTH AND SAFETY

- To be familiar and competent with procedures associated with Health and Safety matters relevant to the department.
- To be respectful of Health and Safety matters associated with other departments should you be required to attend.

QUALITY STANDARDS

- To uphold the Quality Management System by understanding and observing the quality policies and procedures
- To understand and perform all work in accordance with the Standard Operating Procedures in order to ensure compliance with all local and national standards of work practice, e.g. UKAS / MHRA / CQC
- To comply with HSL policies pertinent to Clinical Governance and Risk Management.
- To identify opportunities to improve efficiency in own area.
- To assist in the establishment, maintenance and review of the quality management system
- To ensure analytical accuracy and confidentiality of results observing rules laid down by the Data Protection Act.
- To communicate any difficulties or problems to senior staff/Manager promptly.

CONFIDENTIALITY AND DATA PROTECTION

You have a responsibility to comply with the Data Protection Act 1998 and to maintain confidentiality of staff, patients and Trust business.

If you are required to process information, you should do so in a fair and lawful way, ensuring accuracy is maintained. You should hold information only for the specific registered purpose and not use or disclose it in any way incompatible with such a purpose. You should disclose information only to authorised persons or organisations as instructed. Breaches of confidentiality in relation to information will result in disciplinary action, which may include dismissal. Employees are expected to comply with all HSL policies and procedures and to work in accordance of the Data Protection Act 1998. For those posts where there is management or supervision of other staff it is the responsibility of that employee to ensure that their staff receives appropriate training.

CONFLICT OF INTEREST

HSL is responsible for ensuring that the services provided to NHS institutions for patients in their care meet the highest standards. Equally, it is responsible for ensuring that staff does not abuse their official position, to gain or benefit themselves, their family or friends.

EQUALITY AND DIVERSITY

HSL values equality and diversity in employment and in the services we provide. It is committed to promoting equality and diversity in employment and will keep our policies and procedures under review to ensure that the job related needs of all staff working in HSL are recognised. Selection for training and development and promotion will be on the basis of the individual's ability to meet the requirements for the job.

You are responsible for ensuring that HSL's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and services.

STANDARDS OF DRESS

All staff are expected to abide by guidance on standards of dress.

Person Specification

Attributes	Requirements	Essential/ Desirable
Qualifications	<ul style="list-style-type: none"> • First degree in Biomedical or life sciences. • Qualification in Quality Management or equivalent experience of working as part of or leading a quality management team. • Post graduate degree in biomedical sciences. • Registration with HCPC is not essential but is desirable. 	<p>E E</p> <p>E E</p>
Experience	<p>Significant experience of working as HCPC registered Biomedical Scientist within a Biochemistry laboratory.</p> <p>Previous experience of leading on inspections for laboratory regulatory and assessment purposes.</p> <p>Significant experience required in Incident identification, investigation, root cause analysis and CAPA management.</p> <p>Auditing qualification or significant experience.</p> <p>Excellent Report writing experience.</p>	<p>E</p> <p>E</p> <p>E</p> <p>E</p> <p>E</p>
Skills and Abilities	<p>Excellent written and verbal communication skills.</p> <p>Excellent interpersonal skills.</p> <p>Ability to work on own initiative and as part of a team.</p> <p>Numerate.</p> <p>Highly skilled in use of Microsoft Office.</p> <p>Able to write reports concisely and precisely.</p> <p>Excellent attention to detail skills</p> <p>Excellent organisational & record keeping skills</p>	<p>E</p> <p>E</p> <p>E</p> <p>E</p> <p>E</p> <p>E</p> <p>E</p>
Personal Qualities	<p>Highly motivated, effective team player with leadership qualities; , ability to interpret standard requirements in order to align expectations, assign responsibilities and meet targets and deadlines, able to learn and assimilate new information.</p> <p>Commitment to working the hours required to fulfil the job, including flexibility of working.</p>	<p>E</p> <p>E</p>

