Guidance on Quality Management in Laboratories
Institute of Biomedical Science

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As the UK professional body for biomedical science the Institute has established the following guidance on quality management for those responsible for the management and delivery of laboratory services. The Institute believes that quality must be an inherent part of the culture in all laboratories delivering a clinical, diagnostic or reporting service and is not the sole responsibility of a particular individual or grade of staff; quality is the responsibility of all personnel irrespective of grade or seniority. A strong quality culture benefits not just the individual but also the employer and the service user.

The UK health departments have put patient care and safety at the heart of healthcare provision. It is the responsibility of the respective providers and all those involved in the delivery of service and care to deliver safe and high quality patient care. It is the responsibility of the professions themselves to establish those standards of best practice relative to their own service.

The role and responsibilities of the Quality Manager

Quality is central to the delivery of all laboratory services and is achieved through the incorporation of quality systems, quality control and quality assurance in all aspects of laboratory practice. A range of quality standards and accreditation systems are used by laboratories dependent on the service provided. For some, such as UKAS ISO 15189 accreditation, the appointment of a Quality Manager is mandatory. This may be undertaken as a specific quality manager job, or may be included with the duties of a senior role such as Laboratory Manager.

For laboratories approved or accredited by other organisations the appointment of an individual with responsibility for quality management is recommended by the Institute.

The Quality Manager is the individual with responsibility as a management representative for ensuring all aspects of quality within a quality management system function correctly. However, all staff are responsible for quality and all senior staff are expected to actively monitor and participate in all quality related activities in their section.

The role and responsibilities of the Quality Manager include development and monitoring of key quality indicators, key performance indicators, business continuity plans, contingency plans, assessing risks to the functioning of the department or quality of the work and risk mitigation. It is a broad role.

The Institute recommends that the Quality Manager holds a recognised quality management qualification such as the Institute’s Certificate of Expert Practice in Quality Management, in addition to a Masters level qualification such as an MSc.
or the Institute’s Higher Specialist Diploma in either a scientific specialism or in Leadership and Management.

The level at which a Quality Manager is required to operate is dependent upon the needs of an individual trust, hospital, health board or network and the activities undertaken in the laboratory. This can range from duties confined to a single pathology discipline undertaken as part of a range of laboratory responsibilities or may cover all pathology disciplines within a hospital service or network.

The Quality Manager is an integral part of the overall laboratory management team and, within this structure, will oversee implementation, development and co-ordination of quality processes as described in the quality policy and manual. These include adherence to relevant professional standards and guidelines, and involvement with clinical governance issues and audit, as well as providing advice and being a focus for all issues relating to quality in the laboratory. The Quality Manager must be aware of any current and evolving legislation and aim to ensure that quality systems meet the requirements of this legislation. Specifically, the Quality Manager must identify and make the executive laboratory management team aware of any shortfall in resources. This can relate to the use of staff and non-staff resources within specific disciplines or across pathology where the Quality Manager is responsible for all pathology disciplines within a hospital service or network. Depending on the regulations applicable, it may require an independent quality function to manage key aspects of the quality system e.g. document control, non-conformance management.

The level and scope of responsibilities that fall to the Quality Manager make this a senior role involving specialist knowledge and expertise. The grade at which an individual is appointed will be determined locally according to the requirements of the post.

**Quality governance arrangements**

Management structures will vary according to local preference and need. However, it is essential that the working arrangements of the Quality Manager are not compromised by conflict of interests. It is expected that the Quality Manager will be responsible to the most senior person in the executive laboratory management team and in a position which facilitates direct reporting and advice to the Clinical Director. Specific blood and tissue regulations and standards e.g. The Rules and Guidance for Pharmaceutical Manufacturers 2014 (GMP Guide) will require that the Quality Manager post be full time and independent of production.

In organisations where there is an individual Quality Manager across all laboratory disciplines it is important for that individual to be confident of uniformity of understanding and implementation of the laboratory quality policy. To this end the Quality Manager is advised to establish a committee to oversee quality, if one does not already exist, in line with the organisational governance structure.
This is of specific benefit when responsible for quality across a range of disciplines and should be made up of discipline specific quality assurance officers where this role is carried out at a departmental level. In organisations that have a Quality Manager for each discipline within clinical laboratory medicine the role of the Quality Manager is effective at a more ‘local’ level and is primarily concerned with issues relating to appropriate laboratory accreditation and to assist with audits. This role is carried out in co-operation with laboratory management. The role of a discipline specific Quality Manager for a multisite and/or networked service would be similar that described for a multidisciplinary Quality Manager as described above.

**Clinical Governance**

Clinical care must conform to national evidence based standards. Clinical governance can be described as making sure that these standards are met. In order to emphasise the importance of laboratory medicine in clinical governance, the Institute recommends that in organisations where there is a single clinical laboratory Quality Manager, or a lead Quality Manager, this individual should be a member of the appropriate committee dealing with clinical governance. There may be a single Clinical Governance committee/group or there may be other groups in larger organisations. The Quality Manager will provide the bi-directional link between pathology and the wider organisation, reporting to/from pathology management. Whether within a clinical laboratory directorate or an individual laboratory department, Quality Managers must be involved in ensuring that regular clinical governance and audit meeting are held. This is essential to plan and review audit projects and in helping to organise the presentation of laboratory/clinical audits.

**Information Systems**

Information systems include the management of data and records contained in both computer and non-computerised systems. Laboratory management will ensure that documented procedures for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records are in place. Such procedures shall guarantee that the laboratory has access to the data and information necessary to provide a service which meets the needs and requirements of the user.

The Quality Manager will approve the validation of such procedures ensuring compliance with relevant legislation and guidance is built-in e.g. GAMP5.

Procedures must define the time period that various records pertaining to the quality management system in keeping with specific guidance for both pathology and other records.

In accordance with the Data Protection Act 1998 and Caldicot 2, systems must ensure that the confidentiality of patient information is maintained at all times.
Communications and Liaison

Good communication is the key to quality. The Quality Manager must, with the Laboratory Manager, develop a strategy to ensure there are effective mechanisms in place for the dissemination of information within the laboratory and also between the laboratory and laboratory service users. In conjunction with the Laboratory Manager, the Quality Manager must ensure there is a system in place for collecting staff suggestions and for giving feedback on actions resulting (or not).

It is desirable* that the role of the Quality Manager is recognised outside of the clinical laboratory and that provision exists for laboratory representation by the Quality Manager on appropriate trust or health board committees. This is especially important in clinical governance as mentioned previously. It is essential that the Quality Manager ensures, through co-operation with professional colleagues, that the needs and requirements of laboratory users are met.

*this role may be carried out by the Pathology Manager, who may not be the Quality Manager.

Quality Manual

The Quality Manual is a key document that serves as an index to laboratory documentation and describes the quality management system of the laboratory. The Quality Manager must ensure that an effective document control system is in place and operational, including the quality manual and all procedures and records in addition to those that relate to training and health and safety. The Quality Manager should therefore develop a comprehensive quality system which is ‘owned’ by everyone within laboratories and which satisfies the requirements for quality systems as necessary for a number of standards and regulations.

Appraisals and Personal Development Plans

Within laboratories an effective appraisal system is an effective means of enabling manager/staff communication. Liaison between the Laboratory Manager, Quality Manager and Laboratory Training Officers is essential to the process. While the Quality Manager is responsible for ensuring that an appraisal system is in place, it is the laboratory management who has responsibility to ensure that PDPs are implemented and operationally effective. This is a corporate requirement and the responsibility is on laboratory managers through the operational leads. Neither the Quality Manager nor the Training Officers have the authority to ensure PDP’s are implemented and operationally effective. PDPs should, however, include training, where required, in the quality management system, ensure that there are competence assessments and include continuing professional development.
Complaints, Compliments, Incidents and Error Reporting

All complaints, both formal and informal, should be recorded and acted upon. Complaint management is a corporate responsibility and it is the responsibility of the employing organisation to ensure that there is a system in place. It is the responsibility of the Laboratory Manager to ensure trust/employer procedures are followed and to ensure that corrective or preventative action is taken and outcomes are recorded. It is recommended that a similar process is established to record compliments of the service, and to disseminate this information to laboratory management. Again, the link provided by the Quality Manager and all relevant organisational committees/groups is important to ensure that this aspect of the quality management system is operating effectively. It is the expectation that the Quality Manager would be involved in incident investigations, root cause analysis, trend analysis, ensuring preventative actions and corrective actions are taken and ensuring that learning is shared across the organisation.

Point of Care Testing

Point of Care Testing (POCT) refers to analytical processes performed outside the clinical laboratory. Where this is a service managed under contract by the laboratory it must be monitored and supervised by qualified staff of a local ISO 15189 (or Clinical Pathology Accreditation (CPA) Ltd) accredited clinical laboratory. Laboratory management, including the Quality Manager, must have the authority to develop, manage and monitor systems within the trust, hospital or health board that enable the implementation of POCT, where relevant, and to ensure that all current professional guidelines are implemented within POCT systems. ISO 22870 is the International Standard for POCT systems.

Health and Safety

The Quality Manager will need to know that the trust/health board health and Safety Manager are addressing health and safety issues across the organization, and that a co-ordinated approach to health and safety is cascaded down to departmental health and safety officers to be implemented at a local level. The Laboratory Manager is responsible for ensuring that appropriate health and safety measures are in place, while the health and safety officer, with the Laboratory Manager, ensure their effective implementation. The Quality Manager has a role in the monitoring of health and safety risks to the department, because these impact on the QMS and therefore the department’s ability to maintain compliance with the standard. As such, the Quality Manager should be a member of the Pathology Safety Committee.
References

Royal College of Pathologists: The retention and storage of pathological records and specimens

Blood Safety and Quality Regulations 2005 (as amended)

Human Tissue (Quality and Safety for Human Application) Regulations 2007

ISO 15189 (2012)

GAMP® Good Automated Manufacturing Practice

Human Tissue Act 2004