Institute of Biomedical Science

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Guidance on the roles of Quality Personnel in Clinical Laboratories

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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 patient care to ensure this service is safe and of high quality. It is the responsibility of the professions themselves to establish those standards of best practice relative to their own service.

1. The role and responsibilities of quality personnel

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. ISO15189:2022 requires laboratories to have personnel with the authority and responsibility for implementation, maintenance and improvement of the laboratory management system alongside other quality-related tasks. The quality management responsibilities may be assigned to an individual, such as a specific quality manager, or may be included with the duties of other laboratory roles such as laboratory managers or senior biomedical scientists.

The requirement for a specific quality manager position has been removed from the ISO15189 standard however, for laboratories approved or accredited by other organisations the appointment of a biomedical scientist (or biomedical scientists) with responsibility for quality management is strongly recommended by the Institute.

The following refers to a single quality manager but may be applied to one or more roles.

The quality manager is the individual with responsibility for ensuring the quality management system (QMS) is established, implemented, maintained and improved upon. The role entails acting as a management representative to ensure 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.

The role and responsibilities of the quality manager include, but are not limited to, development and monitoring of key quality indicators, key performance indicators, audit schedules, business continuity plans, contingency plans, assessing risks to the functioning of the department or quality of the work and risk mitigation. It is an extensive role.

The Institute recommends that the quality manager is a biomedical scientist and 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 Leadership and Management.

The level at which a quality manager is required to operate is dependent upon the needs of an individual hospital, trust, 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. Regardless of level, the quality manager must have the authority to report to laboratory management at a level at which decisions are made on policy, objectives, resources and on the performance of the QMS and any need for improvement.

The quality manager is an integral part of the overall laboratory management team and, within this structure, will oversee the 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, revised national policies or guidelines and any updates to standards and aim to ensure that quality systems meet the requirements. 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/organisation or network. Depending on the regulations[1, 2] 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 makes 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.

2. 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[1] and tissue[2] regulations and standards e.g., The Rules and Guidance for Pharmaceutical Manufacturers 2022 (MHRA Guide)[3] 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 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 to that described for a multidisciplinary quality manager above.

In the context of ISO 15189:2022, the role of a quality manager in risk management is critical to ensuring the quality and safety of laboratory processes and results. This includes understanding the revised standard's provisions related to risk management and ensuring that the laboratory's processes align with these requirements.

Based on the results of risk assessments, the quality manager collaborates with relevant laboratory staff to develop risk management plans. These plans outline strategies and actions to mitigate, monitor, and control identified risks. They also establish criteria for acceptable risk levels.

3. Clinical Governance

Clinical governance is the system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish.

Clinical care must conform to national evidence-based standards. Clinical governance can therefore be described as ensuring these standards are met. In order to emphasise the importance of clinical pathology laboratories in clinical governance, the Institute recommends that in organisations where there is a 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 pathology laboratory directorate or an individual laboratory department, quality managers must be involved in ensuring that regular clinical governance and audit meetings are held. This is essential to plan and review audit projects and in helping to organise the presentation of laboratory/clinical audits.

4. 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 of various records pertaining to the quality management system in keeping with specific guidance for both pathology and other records.[1]

In accordance with the General Data Protection Regulations (GDPR), May 2018 and Caldicott, systems must ensure that the confidentiality of patient information is maintained at all times.

5. 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 between the laboratory and laboratory service users. This ensures ongoing effectiveness of the service provided and allows for assessment of user feedback.

In conjunction with the laboratory manager, the quality manager must also 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 laboratory and that provision exists for laboratory representation by the quality manager on appropriate hospital, trust or health board committees via the Governance Committee or equivalent. 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)

6. Quality Manual

Although no longer a requirement of ISO15189:2022, the quality manual is considered a useful document that serves as an index to laboratory documentation and describes the quality management system of the laboratory. This document should provide staff and any assessor of the service an understanding of the management's commitment to quality. 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.

7. Appraisals and Personal Development Plans (PDPs)

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. The laboratory manager is responsible for ensuring that an appraisal system is in place, and that personal development plans (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 QMS, ensure that there are competence assessments and include continuing professional development.

8. Continuous Quality improvement

It is all too easy for the Quality Manager to be tagged as the person for maintaining accreditation within an organisation however quality management must go beyond the accreditation cycle.

ISO 9000 contains seven quality management principles which form the basis for organisations wishing to control quality in a systematic and process-based manner. The

seventh of the principles is improvement and the role of the quality manager must include quality improvement.

Continuous quality improvement (CQI) is a quality management philosophy that encourages all team members to continuously ask what can be done better. CQI builds on existing quality management approaches but emphasises that internal and external customer satisfaction is paramount, and that problems are caused by processes, not people.

A continuous quality improvement programme aims to ensure that all team members, employees, managers, and other stakeholders feel consistently empowered to improve efforts and results.

A commonly recognised problem in any process is variation. Variation in procedures causes variation in outcomes. CQI and all quality management philosophies seek to make processes consistent. When output is consistent, teams can begin to improve processes.

Improvement should be part of the culture of the organisation and a natural part of how people perform their jobs. Improvement doesn't only mean success in a one-off project; rather, it is an ongoing effort, concurrent with regular duties.

With CQI comes change management and inevitably the quality manager must be skilled in both to achieve an effective quality management system.

9. Complaints, Compliments, Incidents and Error Reporting

A complaint will arise when the quality of service provided by the service has not met the expectations of its users. Complaints should be welcomed as an opportunity to identify quality problems, and put them right, thus improving the service offered.

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 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 and staff. 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 to prevent reoccurrence.

10. 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 accredited clinical laboratory. Laboratory management, including the quality manager, must have the authority to develop, manage and monitor systems within the hospital, trust or health board that enable the implementation of POCT, where relevant, and to ensure that all current professional guidelines are implemented within POCT systems. ISO15189:2022 is the international standard which now includes POCT.

11. Health and Safety

The quality manager will need to know that the health and safety manager of the hospital/trust/ health board/organisation is addressing health and safety issues across the organization, and that a coordinated 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 as these impact on the QMS and therefore the department's ability to maintain compliance with the standard. As such, it is desirable that the quality manager should be a member of the pathology safety committee.

References:

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

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

3. Rules and Guidance for Pharmaceutical Manufacturers and Distributers 2022 (MHRA Orange Guide)

Further reading

1. Blood Safety and Quality Regulations 2005 as amended

2. BS EN ISO 15189:2022

3. GAMP® Good Automated Manufacturing Practice

4. Human Tissue Act 2004

5. UKHSA: Clinical Governance

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