

Implementing Compliance Management Solutions to Achieve Laboratory Accreditation

Executive Summary

Government initiatives to modernise pathology services have required laboratories to adopt a compliance management approach that will help to ensure that patients obtain the services they need and in the place that they need them. In response, laboratories have implemented compliance management solutions with a view to decreasing inappropriate variation in service delivery and increasing opportunities for continual improvement.

In addition, pathology-specific quality assurance standards, such as ISO 9001, ISO 17025 and ISO 15189, require laboratories to implement and maintain laboratory accreditation systems. Within the UK, Clinical Pathology Accreditation (UK) Ltd (CPA) is nationally recognised as providing a set of minimum quality standards for pathology laboratories.

Impact on pathology

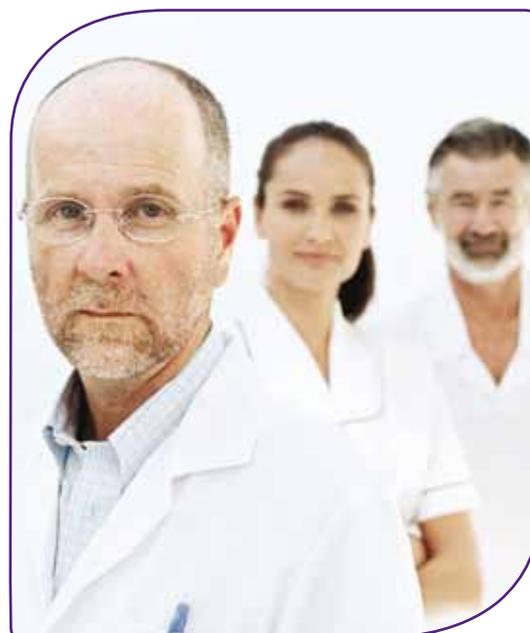
- Laboratories must implement laboratory accreditation systems to satisfy government pathology modernisation requirements
- UK government recommend CPA as the most effective method by which laboratories can manage quality
- Laboratory accreditation is a key component of a hospital's procedures for clinical risk reduction
- Laboratory accreditation compliance is increasingly difficult to demonstrate with paper-based systems

Impact on laboratories

- Laboratory accreditation systems must be independently appraised and audited regularly
- Laboratories must implement, maintain and review adequate safety procedures
- Laboratories must support quality procedures with documentation and records
- Laboratories must identify and address opportunities for continual improvement

Compliance with national standards is a requirement in modernising pathology services to ensure that patients have access to services when and where they need them. Implementing paper-based management systems to maintain and review laboratory accreditation systems leads to problems reoccurring and risks increasing, which could impact the quality of patient care.

As the importance of regulatory compliance increases, laboratories are implementing compliance management solutions to manage the maintenance and review of laboratory accreditation systems, achieving a recognised standard of practice and assuring users of the high quality of services available.



Laboratory Accreditation - An Introduction

Within the healthcare environment, pathology laboratories provide the foundation for evidence-based treatment and care upon which patients depend; in the UK, it is estimated that up to 70% of patients' diagnoses depend on pathology laboratory tests. With such a vital role within Healthcare, pathology laboratories must ensure that the services they provide are fit for purpose and that opportunities for continual improvement are readily embraced.

The implementation of quality assurance into all aspects of laboratory practice has become second nature within pathology. Within the UK, Clinical Pathology Accreditation (UK) Ltd (CPA) is nationally recognised as providing a set of minimum quality standards for pathology laboratories.

Government initiatives such as the Pathology Modernisation Programme and European directives such as the EU Blood Directive 2002/98/EC, as well as mandating pathology accreditation, aim to stimulate and encourage modernisation, addressing issues within the services including:

- increasing demand for services
- lack of investment
- deteriorating laboratory infrastructure
- inequalities of pathology provision

Compliance management and its tools and techniques have long been recognised as an effective method of ensuring that the delivery of Pathology services meets patients' needs. Compliance with national standards is now a requirement in modernising pathology services, to ensure that patients can obtain the services they need and in the place they need them.

Government initiatives have positioned CPA compliance at the centre of modernising pathology. However, laboratory accreditation systems are often very resource-intensive, requiring a great deal of time and effort to ensure that they are maintained effectively, and the harsh reality is often:

- significant time, effort and cost required to manage the Document Control process manually
- audit process is too complex and resource-intensive, with increased time required for preparing, conducting, reporting and following-up
- maintaining and tracking staff training and competence records increases the intensive administrative workload required to manage accreditation
- incidents are not defined accurately and root causes are not identified effectively, resulting in difficulties in understanding the impact of incidents on laboratory processes
- opportunities for continual improvement cannot be identified effectively

Facilitating the Role of the Quality Manager

With the introduction of government initiatives mandating a quality assurance approach to pathology management, within the laboratory accreditation system, the role of the quality manager is of paramount importance in ensuring its success.

According to the Institute of Biomedical Science's Guidance on the Role of the Pathology Quality Manager, 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 relating to training and health and safety
- regular clinical governance and audit meetings are held
- a strategy is developed to ensure there are effective mechanisms in place for the dissemination of information within the laboratory and also between the laboratory and the service users
- an appraisal system and Personal Development Plans are in place
- a system is in place for the recording and addressing of complaints, incidents and errors and to ensure that corrective or preventative action is taken and outcomes are recorded

Solutions that enable pathology laboratories to manage clinical accreditation enable radical reductions in the time required to achieve certification to standards, and dramatically decrease the duplication of effort in complying with legal and regulatory requirements. By implementing a compliance management solution to manage clinical accreditation, compliance with standards, including CPA, can be achieved, as well as enhancing the maintenance and improvement of clinical accreditation.

Compliance Management Solutions in Managing Accreditation

With government pressure to comply with pathology-specific standards increasing, laboratories can no longer rely on traditional pathology management systems to manage accreditation. The resources required in maintaining such systems and, more importantly, their rigid structure means that their administration is extremely time-consuming and detailed analysis and understanding of the laboratory accreditation system is extremely difficult.

In addition to offering a proven solution for pathology-specific quality assurance standards such as ISO 9001, ISO 17025 and ISO 15189, compliance management solutions facilitate CPA activities. With a compliance management solution that enables the efficient and effective management of clinical accreditation, pathology laboratories can put effective systems and controls in place to:

- ensure effective diagnosis through accurate analytical work
- improve patient care with a streamlined, efficient and effective laboratory
- reduce exposure to risk through due diligence and regulatory compliance

By implementing a compliance management solution to manage clinical accreditation, pathology laboratories can maintain and improve processes such as document control, corrective and preventive action, audits and management review.

Controlling documentation

With a traditional pathology management system, document control cycle times can increase as a result of inactive and obsolete documents remaining in circulation, which can lead to staff following incorrect procedures and could impact the quality of patient care. Staff are less likely to request changes to documents as they have limited access to the change control process and staff ownership is difficult to encourage. Document storage and disposal costs can also rise as the volume of paper-based documents increases.

A compliance management solution enables laboratories to:

- increase access to controlled documents by providing global access to a central Document Register
- reduce document control costs by eliminating printed copies of documents and automating administration tasks
- enhance document accuracy through increased staff input, with inaccuracies being spotted and suggestions being received by automating the change request process
- reduce the risk of document-related errors by extending access to your system throughout the Trust

Managing audits

Information in a traditional pathology management system takes a great deal of resources to gather and analyse, which can result in an increase in preparation time and a decrease in efficiency. Longer preparation times can lead to audit cycle times increasing and a lack of ownership can lead to staff overlooking an increasing number of audit findings.

A compliance management solution enables laboratories to:

- decrease the amount of management time it takes to prepare for any pathology laboratory audit by automating audit scheduling and notification
- reduce the administrative time and effort spent on every aspect of the entire audit programme by automating the entire audit lifecycle
- reduce the number of findings being overlooked through automatic email notification and escalation
- enhance audit finding analysis to increase time available for addressing incidents of risk

Addressing incidents of risk

The lack of tools for analysing corrective action information in traditional pathology management systems can make it difficult to find root causes, and analysis requires greater resources, leaving you with less time to address incidents of risk. Difficulties in identifying how and where resources should be allocated can lead to escalating costs, waste and could impact the quality of patient care. Ineffective communication and a lack of staff ownership can result in actions being overlooked.

A compliance management solution enables laboratories to:

- enhance the accuracy of root cause definition for every incident through real-time analysis capabilities
- reduce the number of incidents being overlooked through automatic email notification and escalation
- increase awareness of poor quality costs to direct resources at areas requiring most immediate attention, addressing costly rework issues
- reduce incident analysis time and effort to increase time available to address incidents of risk and continual improvement

Managing training records and professional development

Storing and retrieving information in a traditional pathology management system requires increased time and effort to maintain accurate records. Tracking and maintaining training requirements in a traditional pathology management system can cause difficulties in identifying and approving personal development plans (PDPs). Difficulties in maintaining and increasing the competence of laboratory staff can expose staff and patients to increased risk. Failing to notify appropriate persons of approaching training can make it difficult to track and maintain personal and professional development.

A compliance management solution enables laboratories to:

- access all historical training records from a central register, facilitating quick and easy storage and retrieval
- track and maintaining all laboratory staff training requirements with a centralised training management system
- increase the competence of laboratory staff through detailed training gap analysis
- automatically notify appropriate persons of approaching training ensuring continual personal development (CPD) is maintained

Identifying continual improvement

Traditional pathology management systems can leave you unable to analyse incidents of risk by occurrence or severity, which can lead to an increase in the occurrence of incidents of risk and could impact the quality of patient care. Without access to up-to-date information, it's difficult to identify opportunities for continual improvement and, without the regular review of corrective actions and audit findings, problems will reoccur and risks will increase.

A compliance management solution enables laboratories to:

- analyse all incidents of risk by occurrence and cost to address issues at a laboratory, ward, surgery or consultant level
- identify improvement opportunities, reduce costs and repeat failures through trended root cause analysis
- provide continual improvement analysis 'on demand' with access to complete up-to-date information
- enhance the efficiency of your management reviews by enabling 'on demand' analysis of audit findings and incidents of risk

Conclusion

With the introduction of government initiatives mandating a quality assurance approach to pathology management, the laboratory accreditation system is of paramount importance in ensuring that the services provided by pathology laboratories are fit for purpose and that opportunities for continual improvement are readily embraced.

Compliance management and its tools and techniques have long been recognised as an effective method of ensuring that the delivery of Pathology services meets patients' needs. Compliance with national standards is now a requirement in modernising pathology services, to ensure that patients can obtain the services they need and in the place they need them.

In addition to offering a proven solution for pathology-specific quality assurance standards such as ISO 9001, ISO 17025 and ISO 15189, compliance management solutions facilitate CPA activities. With a solution that enables the efficient management of clinical accreditation, pathology laboratories can put effective systems and controls in place to:

- ensure effective diagnosis through accurate analytical work
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Contact us now on +44 1355 593 400 or at pathology@gaelquality.com to discuss how our compliance management solutions can add significant value to your clinical accreditation efforts.