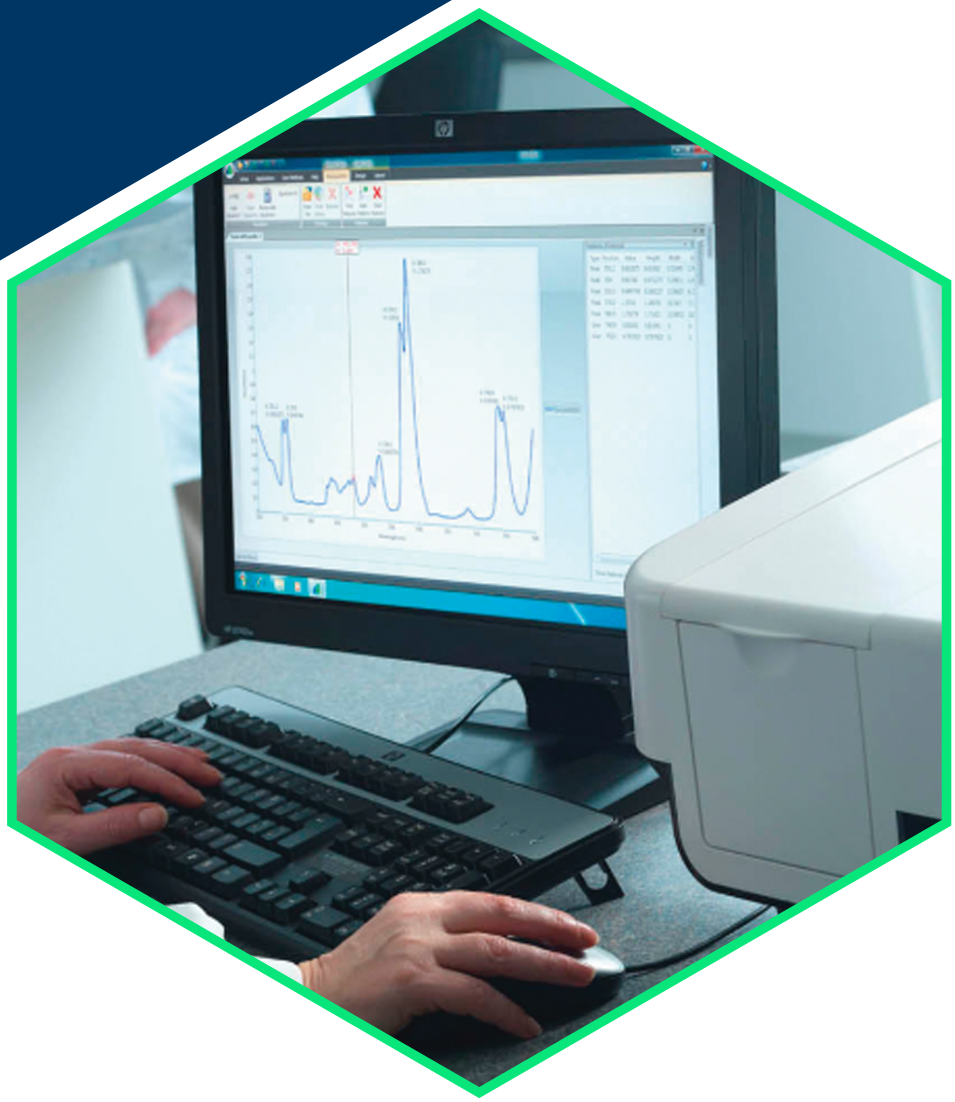
QUALITY MANAGEMENT DIGITAL SPECIALIST PORTFOLIO MODULE

IBMS Institute of Biomedical Science



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Module Title	Quality Module
Module code	7045
Rationale/ Aims	The aim of this module is to ensure candidates understand the role and application of quality management practices in the laboratory. The candidate will understand how quality management processes relate to laboratories and pathology departments, including POCT and how this contributes to healthcare in general and improves patient outcomes. The candidate will understand the principles of quality management including internal and external quality control and external quality assessment and be able to demonstrate this in practice, they will be able to perform audits and understand the processes that follow from the audit. They will be able to apply quality processes in their laboratory to ensure the quality of their own practice as well as that of the department.
Learning outcomes	1. Describe the elements of the laboratory quality management systems (including management of documents and data) and how they relate to patient outcomes. 2. Discuss, relevant to your practice, pre-analytical factors that influence sample acceptance criteria, test results and examples of how process failures are actioned. 3. Discuss the principles of internal quality control, including the use of third-party quality control and alternatives if these are not available, and monitoring for trends and bias. Include the use in comparison of equipment and operators. 4. Discuss internal quality control processes, including the use of appropriate materials, establishing acceptance criteria, use of IQC rules, detection of different types of error conditions and actions undertaken if internal quality controls fail. Use examples from practice where appropriate. 5. Discuss the processes for establishing metrological traceability of tests/targets as applicable and their influence on results. 6. Discuss the principles of external quality assessment (EQA), what to do if no EQA schemes are available for a test, and how to investigate unsatisfactory performance including understanding the UK EQA governance structure, and the escalation of laboratories to the National Quality Assurance Advisory Panel. Use examples from practice where appropriate. 7. Discuss the role of audit in pathology quality processes and explain, using an example from the candidates practice, the audit processes including identifying, investigating, and resolving non-conformances. 8. Explain the potential uses of measurement uncertainty data in pathology and give an example of how this has been calculated in the candidates workplace. 9. Investigate unusual results (e.g. EQA, IQC) and take appropriate action, explain the rationale for the actions taken, demonstrate relevant documentation has been completed appropriately. 10. Discuss the role of quality management in the training and competency of laboratory staff and how it contributes to the accreditation process.
Indicative Content	Candidates must be familiar with laboratory accreditation processes, the role and scope of practice of regulatory and accreditation bodies in pathology (UKAS, MHRA, HTA etc), relevant pathology ISO standards, and the role of independent health regulators relating to medical laboratories.

	Candidates should understand quality management in their workplace and how this relates to patient care. Candidates should be aware of different types of audit, e.g. horizontal, vertical, clinical, examination. Candidates should know how to follow up on quality issues and how they may be resolved. Candidates should understand their scope of practice for investigating and reporting incidents. Candidates should be able to recognise and respond to pre-analytical, analytical and post-analytical errors as applicable to practice. Candidates should understand laboratory risk identification and management and how this relates to patient care. Candidates must be familiar with the principles of In vitro diagnostic medical devices (IVD) selection appropriate for clinical needs.

About this version

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