UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
BISC-510	Laboratory Quality Assurance Management	7.5
Prerequisites	**Department**	**Semester**
None	Life Sciences	Fall
Type of Course	**Field**	**Language of Instruction**
Required (Core)	Biomedical Sciences	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Dr. Christos Petrou Dr. Yiannis Sariayiannis	1st
Mode of Delivery	**Work Placement**	**Corequisites**
Face to Face	N/A	None

Course Objectives:

This course aims to discuss clinical laboratory issues related to administration and management, quality control, and quality assurance to enable students to understand and apply methods and tools within quality management and laboratory safety for accreditation purposes and compliance with regulatory agencies. The main objectives of the course are:

- Explain the role of managing and supervising in a clinical laboratory and the related skills that must be acquired and practiced in such a setting.
- Demonstrate how safety regulations must be integrated into clinical laboratory management and practices.
- Demonstrate how to develop protocols for quality assurance purposes, accreditation, and maintaining accreditation.
- Demonstrate how to evaluate the quality of testing methods, set up standards, and validate test performance specifications.
- Provide guidelines for procedures for calibration and method and equipment performance test specifications verification
- Demonstrate the role of laboratory systems in laboratory data management.

Learning Outcomes:

After completion of the course, students are expected to be able to:

1. Discuss the application of the total quality management concept in service-providing settings.
2. Apply methods and techniques to organize and manage a clinical laboratory.
3. Apply risk assessment to support patient care.
4. Apply methods for quality assurance, including monitoring and evaluating the quality of testing procedures, standardizing operating processes, and establishing reference intervals.
5. Apply validation of test performance specifications and compliance
6. Explain calibrations and quality control for equipment and reagents.
7. Explain the role of the supervisor and the role of clinical laboratory scientists in initial accreditation and maintaining accreditation of a clinical laboratory.
8. Discuss the importance of information for sustainable quality work
9. Describe the role of laboratory systems in laboratory data management.
10. Integrate safety regulation into clinical laboratory management and practices.
11. Describe the ethical principles of providing clinical laboratory services.

Course Content:

1. Organization and Management: Definition, concepts, and function of total quality management. Quality principles.
2. Risk management: Establish the laboratory's processes (pre-examination, examination, and post-examination processes) and apply the principles of risk management to the cycle of laboratory medical care
3. Administration; Laboratory design and organization, Personnel management and code of contact, leadership, and communication
4. Management of laboratory resources (Time, space, equipment, supplies)
5. Management of laboratory data and budget.
6. Safety in the Laboratory: source of hazards, safety, and infection-preventing measures. Waste management.
7. Quality Assurance: Definition and purposes of QA. Internal quality control. Westgard rules
8. External quality control (interlaboratory comparison programmes). Control of referral laboratories.
9. Methods and tools for QA and improvements. Evaluation and audits
10. Validity and appropriateness of pre-examination, examination and post-examination processes (sample collection, transport and sample handling, recording and reporting)
11. Validation and verification of analytical procedure (test methods)
12. Evaluation of results. Reporting and releasing of results. Report contents.

13. Traceability of measurements and calibrations to relevant standards. Suitability, calibration and maintenance of test equipment
14. Laboratory information management
15. Research and development; Intellectual property rights; application of appropriate ethics

Learning Activities and Teaching Methods:

1. Total Quality Management (TQM).
2. Given a personnel problem situation, apply personnel competence assessment and performance to established criteria.
3. Given specific problems, to apply and evaluate external quality control and control on referral laboratories.
4. Given specific problems, to apply internal quality control of analytical procedures (test methods).
5. Given specific problems to apply an audit to an area of a laboratory.
6. Given specific situations, prepare a laboratory budget, including direct and indirect costs, instrument evaluation and cost analysis.
7. Apply verification of analytical procedures (test methods). Write a laboratory procedure and work instruction according to ISO 15189 guidelines.

Assessment Methods:

Assignments, mid-term and final examinations

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
ISO 15189:2012 - Medical laboratories - Requirements for quality and competence	ISO	ISO	2012	**CYS** Cyprus Organisation for Standardisation www.cys.org.cy

Recommended Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
ISO TS 22367:2010 Medical laboratories -Reduction of errors through risk management and continual improvement" - – Recommended	ISO	ISO	2010	**CYS** Cyprus Organisation for Standardisation www.cys.org.cy
LABORATORY QUALITY/MANAGEMENT: A Workbook with an Eye on Accreditation Paperback	Kenneth N. Parson	XLIBRIS	2012	**ISBN-10:** 1479753947 **ISBN-13:** 978-1479753949
A Laboratory Quality Handbook of Best Practices & Relevant Regulations Paperback	Donald C. Singer	ASQ Quality Press	2001	**ISBN-10:** 087389491X **ISBN-13:** 978-0873894913
Principles of Clinical Laboratory Management: A Study Guide and Workbook [Paperback]	Jane Hudson	Prentice Hall	2003	**ISBN-10:** 0130495387 **ISBN-13:** 978-0130495389
Medical Laboratory Management and Supervision, 2nd Edition Hardcover	Lionel A. Varnadoe	Lionel A Varnadoe;	2008	**ISBN-10:** 1605855472 **ISBN-13:** 978-1605855479