Course Title	**Quality assurance and accreditation in biomedical sciences**				
Course Code	ABS206				
Course Type	Compulsory				
Level	BSc (Level 1)				
Year / Semester	4th Semester / 2nd year				
Teacher's Name	Dr Despina Charalambous				
ECTS	3	Lectures / week	2	Laboratories / week	1
Course Objectives	The quality assurance and accreditation course includes understanding of the quality systems used in biomedical sciences and specifically in the clinical laboratories. In addition the course will focus on the principles and applications of good statistical quality control (QC) practices. The aim of this course is to: • cover all the basic elements and tools required to implement the quality system essentials across all phases of the laboratory workflow: preanalytical, analytical, post-analytical. • students will acquire knowledge related to quality and safety controls that are required in specialized areas such as blood bank, clinical microbiology, and molecular diagnostics. • students will become knowledgeable on the accreditation procedures and the International quality standards that specify quality and competence in medical laboratories. • Students will become competent in following and practicing protocols and procedures that comply with quality assurance and laboratory accreditation systems.				
Learning Outcomes	By the end of this course students will be able to: Develop an in depth understanding of the theoretical background of implementing a quality management system in a medical laboratory Understand and implement risk management in all phases of workflow in a biomedical laboratory Apply the basic concept of quality controls and assess the laboratories performance in specialized areas such as: microbiology, biochemistry, immunocytochemistry, hematology, molecular diagnostics. Understand the principles of external quality assessment and proficiency testing Become competent in the validation of quantitative and qualitative testing Trained personnel will improve the efficiency and effectiveness of clinical laboratory services and significantly reduce or eliminate the number of deficiencies.				

Prerequisites	-	Required	-
Course Content	Theory Implementation of the quality management system Risk assessment Internal and external quality control The principles and theoretical background that underpin Clinical laboratory accreditation procedure Steps to follow by the laboratory for maintaining quality assurance Implement validation procedures for quantitative and qualitative testing Individual responsibilities and effective team work Through the use of laboratory exercices/demonstrations/workshops and case studies students will be taught and become competent in executing various standardized methods which form the backbone of clinical laboratory work. These will include : • Microscopy • Spectroscopy/chromatography • PCR • Electrophoresis • ELIZA • Chemiluminescence-Immunoassays		
Teaching	The teaching of the course includes lectures to help students understand the theoretical background and laboratory exercises in order to help them comprehend the range of laboratory diagnostic methods and the main principles which are applied on the various biological samples. Some basic laboratory techniques will be conducted in the Biology and Biochemistry Laboratory using the appropriate laboratory equipment, under the instructor's supervision. Students will also be hosted in Clinical laboratories in order to learn about automation, high throughput analytical instruments and in dealing with the documentation and the critical appraisal of results. Appropriate preparation and demonstration by the laboratory supervisor precedes each laboratory exercise. Assessment of laboratory exercises includes laboratory reports submitted by each student at the end of each lab exercise.		
Bibliography	Textbooks: • Basic Quality Assurance and Quality Control in the Clinical Laboratory by Bruse Wayne, 1st Edition, Little Brown & Co, ISBN 0316112526 • Handbook of Quality Assurance in Laboratory Medicine by Shubangi Tambwekar, 2nd edition, Wolters kluwer india Pvt Ltd, ISBN 9351293319 • ISO 15189:2022 Medical laboratories — Requirements for quality and competence		
Assessment	Course Work 40% • Mid-term Test 20% • Lab reports 20% Final Exam 60% For student evaluation, the overall grade is determined by a written		

	midterm exam (20%), a laboratory grade (20%) and a written final exam (60%). The mid-term exam is carried out between the 6th and 8th week and it mainly includes short answer- questions and problem- solving questions and examines specific modules of the course. As far as the laboratory grade is concerned, it comprises of the evaluation of the laboratory reports (60% of the laboratory grade) submitted by the students after every experiment and a final laboratory examination (40% of the laboratory grade) which mainly includes short answer questions and problem-solving questions. In their laboratory reports, students are asked to describe the experimental procedure, to evaluate and analyse their results and to answer specific questions. The following criteria are taken into account when evaluating laboratory reports: (a) experimental data collection (30%), (b) data analysis (40%), and application of theory to draw conclusions (30%). The final exam of the course is carried out during the 14th-16th week of each semester and includes short answer questions, decision questions, and problem-solving questions regarding all course modules. The final assessment of the students is formative and summative and is assured to comply with the subject's expected learning outcomes and the quality of the course.
Language	Greek, English