TISHK INTERNATIONAL UNIVERSITY
FACULTY OF APPLIED SCIENCE
Department of MEDICAL ANALYSIS,
-2022 Fall
Course Information for MA 315 QUALITY ASSURANCE AND CONTROL

Course Name:	QUALITY ASSURANCE AND CONTROL

Code	Regular Semester	Theoretical	Practical	Credits	ECTS
MA 315	5	2	-	2	3

Name of Lecturer(s)-Academic Title:	Goran Nuri - MSc
Teaching Assistant:	-
Course Language:	-
Course Type:	Main
Office Hours	Thursdays 14:00-16:00
Contact Email:	goran.nori@tiu.edu.iq Tel:07500000000
Teacher's academic profile:	Medical microbiology
Course Objectives:	1- Knowing the basics of Quality Assurance program in medical laboratories. 2- Being familiar with the principles of Quality Control procedures both internal and external that are applied for quantitative, qualitative and semiquantitative tests. 3- Understanding entire set of operations that occur in testing processes including pre-examination, examination and post-examination phases of lab. Investigations which is the path of workflow. 4- Exploring the essential building blocks of the Quality Management System Model (QMS) which has been adopted by WHO, CLSI and ISO. 5- Discovering the most proper way and method to deal with different clinical samples, specimens and biopsy of different human organs and structures.
Course Description (Course overview):	The goal of this course is to provide students with a focused exploration of the regulatory guidance and how they are applied in the medical Analysis field, devices, combination and biotechnology industries. This course will provide students the opportunity to understand the application of the regulations to Quality systems and their relationship to the Quality Assurance and Quality Control functions supporting manufacturing processes.

COURSE CONTENT

Week	Hour	Date	Topic
1	2	4-7/10/2021	Introduction to Quality Assurance and Control
2	2	10-14/10/2021	The Quality Management System Model
3	2	17-21/10/2021	Sample management
4	2	24-28/10/2021	Process control
5	2	31/10-4/11/2021	Quality Control
6	2	7-11/11/2021	Quality control for quantitative tests
7	2	14-18/11/2021	Midterm Exam
8	2	21-25/11/2021	Midterm Exam
9	2	28/11-2/12/2021	Assignment (a report after visiting medical laboratories)
10	2	5-9/12/2021	Laboratory Personnel
11	2	12-16/12/2021	Management of laboratory errors
12	2	19-23/12/2021	Process improvement
13	2	26-30/12/2021	Documents and records
14	2	2-5/1/2022	Laboratories Equipment

15	2	9-13/1/2022	Final Exam
16	2	16-20/1/2022	Final Exam

COURSE/STUDENT LEARNING OUTCOMES

1	Perform all processes and procedures in the laboratory in the best possible way to achieve the highest level of accuracy and reliability.
2	2- Organized the structure and management aspects of the laboratory so that quality policies can be established and implemented
3	3- Select the right equipment, install it correctly, ensure that new equipment works properly, and have a system for maintenance
4	4- Manage the information (data) carefully to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health care providers.
5	5- Establish a system to detect laboratory errors and problems, to handle them properly, and to learn from mistakes and take action so that they do not happen again.

COURSE'S CONTRIBUTION TO PROGRAM OUTCOMES

(Blank : no contribution, I: Introduction, P: Profecient, A: Advanced)

	Program Learning Outcomes	**Cont.**
1	Evaluate clinical laboratory data by interpreting laboratory results and relating the data to various disease states.	I
2	apply principles of evidence-based medicine to determine clinical diagnoses.	I
3	apply the basic principles of gross and microscopic anatomy, physiology, biochemistry, immunology, microbiology/virology.	P
4	formulate and implement acceptable treatment modalities to various disease states.	P
5	use technology effectively in the delivery of instruction, assessment, and professional development.	P
6	exhibit essential employability qualities by demonstrating laboratory safety, analyzing laboratory results, and displaying professional conduct.	P
7	exhibit organizational skills, accountability, and ethical behavior.	P
8	apply skills needed in operating laboratory equipment for testing, assessing quality assurance for lab equipment, and adhering to standard safety practices in the laboratory environment.	P
9	apply problem-solving and decision-making skills.	A
10	apply and promote health policies and regulatory standards in the field career.	A
11	develop research in the field of medical analysis using qualitative and quantitative methods.	A

Prerequisites (Course Reading List and References):	4- ISO 15189:2007. Medical laboratories–particular requirements for quality and competence. Geneva: International Organization for Standardization, 2007.
Student's obligation (Special Requirements):	Students are expected to attend all classes of this course (without exception). A prior approval is required for class absence except for emergencies.
Course Book/Textbook:	1- Laboratory Quality Management System© World Health Organization 2011 2- Basic Lessons in Laboratory Quality Control, by Greg Cooper, CLS, MHA, Published by Bio-Rad Laboratories, Inc. 2008. 3- CLSI/NCCLS. A quality management system model for health care; approved guideline—second edition, CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.
Other Course Materials/References:	4- ISO 15189:2007. Medical laboratories–particular requirements for quality and competence. Geneva: International Organization for Standardization, 2007.
Teaching Methods (Forms of Teaching):	Lectures, Presentation, Assignments, Case studies, , ,

COURSE EVALUATION CRITERIA

Method	**Quantity**	**Percentage (%)**
Attendance	1	5
Participation	1	10
Quiz	2	5
Homework	1	5
Midterm Exam		30
Midterm Exam(s)	1	30
Final Exam	1	40

Total	**100**

Examinations: True-False, Fill in the Blanks, Multiple Choices, Short Answers, Matching, , ,

Extra Notes:

ECTS (ALLOCATED BASED ON STUDENT) WORKLOAD

Activities	Quantity	Workload Hours for 1 quantity*	Total Workload
Theoretical Hours	16	2	32
Practical Hours	16	0	0
Final Exam	1	2	2
Attendance	1	5	5
Participation	1	2	2
Quiz	2	1	2
Homework	1	10	10
Midterm Exam			0
Midterm Exam(s)	1		0
Total Workload			**53**
ECTS Credit (Total workload/25)			**2.12**

Peer review

Signature:	Signature:	Signature:
Name:	Name:	Name:
Lecturer	Head of Department	Dean