



The University of Jordan

Accreditation & Quality Assurance Center

COURSE Syllabus

1	Course title	Pharmaceutical Regulations and Ethics
2	Course number	1202517
3	Credit hours (theory, practical)	2 (theory)
	Contact hours (theory, practical)	2 (theory)
4	Prerequisites/corequisites	Prerequisite: 1203364 (Pharmacology 2)
5	Program title	BSc in Pharmacy and PharmD
6	Program code	
7	Awarding institution	The University of Jordan
8	Faculty	Pharmacy
9	Department	Pharmaceutics and Pharmaceutical Technology
10	Level of course	Undergraduate
11	Year of study and semester (s)	Second semester of the 5 th year
12	Final Qualification	BSc in Pharmacy or PharmD
13	Other department (s) involved in teaching the course	
14	Language of Instruction	Arabic/English
15	Date of production/revision	2016

16. Course Coordinator:

Dr. Bashar Alkhalidi
 Office number: 208
 Office hours:
 phone numbers: 23334
 Email address: b.khalidi@ju.edu.jo

17. Other instructors:

Dr. Alaaldin M. Alkilany
 Office number:226
 Office hours: 12-1:00 daily
 phone numbers: 23320
 Email address:a.alkilany@ju.edu

18. Course Description:

This course is an introduction to existing laws and regulations governing the practice and ethics of pharmacy. It covers the Jordanian laws that control importing, exporting, handling, manufacturing pharmaceutical dosage forms as well as basic codes of ethics and good practice that pharmacist should be covered to prepare students from future practice. Moreover it covers the most relevant international regulatory guidance such as FDA and EMEA.

19. Course aims and outcomes:

<p>A- Aims:</p> <p>1. Provide our students with a good awareness and understanding of pharmaceutical legislation in Jordan</p> <p>2. Provide our students with the main issues of global pharmaceutical legislation and codes</p> <p>B- Intended Learning Outcomes (ILOs): Upon successful completion of this course students will be able to ...</p> <p>A. Knowledge and Understanding: Student is expected to familiarize with: A1. Regulations pertaining to the accreditation of manufacturing sites A2. Regulations pertaining to the Importation and use of Medical Supplies, including: Antiseptics and Disinfectants A3. Regulations pertaining to serums-containing pharmaceutical products, vaccines and Biological Materials</p> <p>B. Intellectual skills (cognitive and analytical): Student is expected to B1. Recognizes the differences between the various global regulations B2. Compare Jordanian regulations to the international regulations (FDA, EMA).</p> <p>C. Subject specific skills</p> <p>D. Transferable Skills: Student is expected to D1. Develop of problem solving and critical thinking skills. D2. Use oral communication to effectively transmit ideas and conclusions to a scientific audience</p> <p>C- Course Competencies:</p> <ol style="list-style-type: none"> 1. Identify valid and up-to-date drug laws and regulations 2. Characterise the national health care system and the role of the pharmacist and other healthcare professionals 3. Identify the principles of intellectual property 4. Abide by appropriate drug policies and regulations 5. Ensure patient confidentiality 6. Respect the legal rights of patients 7. Provide patients with equal services and treatment regardless their cultural or religious differences

20. Topic Outline and Schedule:

Topic	Week	Instructor	Achieved ILOs	Evaluation Methods	Reference
An Introduction about the pharmaceutical legislation in Jordan	1 st	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Medicine and pharmacy Law	2 nd	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
The Amended Regulations of the Accreditation Regulations of manufacturing sites: Reevaluation,	2 nd	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3

and Canceling the Accreditation rules of the year 2001					
The Amended Regulations of the Importation and use of Medical Supplies, including: Antiseptics and Disinfectants of the year 2011	2 nd	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
The Amended Regulations of pharmaceutical Registration, serums, vaccines and Biological Materials	3 rd	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Herbal Preparations and Natural Products License to the year 2011	3 rd	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Preparations used in the Nuclear Medicine Regulations	4 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
The Regulations and Criteria Related to Pharmaceutical prices, prices Renewal, and objections against Pricing Rule to the year 2012	5 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Pharmaceutical Preparations involving Vitamins and/or Minerals to the year 2008	5 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations and Criteria of the Primary Materials of Pharmaceutical Manufacturing Control	6 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Medical Prescription	7 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of considering the medicament as having Therapeutic Advantage	8 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of the use of unregistered and Imported Medicaments	9 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Requirements of technology transfer to medicaments	9 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B &D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Cosmetics	10 th	Dr. Bashar Alkhalidi	A & B &D	Exam, Quiz,	1 & 2 & 3

		Dr. Alaaldin Alkilany		Discussions	
Regulations, foundations, and criteria of the use of Infant Milk, special formulas and complementary foods,	10 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Law of Conducting pharmaceutical studies	11 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations and Requirements to License Authorities and Labs Accreditation.	12 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Drugs and Mental Substances Law	13 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
The Trade Marks of the Registered Medicament involving Drugs and Mental Substances	14 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Drugs Preparations and Disposal in community Pharmacies and Governmental and Private Hospitals	14 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Chemical Precursors	15 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Regulations of Using sedative and psychological medicaments	15 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3
Final exam	16 th	Dr. Bashar Alkhalidi Dr. Alaaldin Alkilany	A & B & D	Exam, Quiz, Discussions	1 & 2 & 3

21. Teaching Methods and Assignments:

Teaching Methods	Learning Skills	
Lectures and Discussions,	Critical thinking	
Assignments	Scientific reasoning	
Presentations	Digital literacy	
	Communication skills	
	Problem-solving skills	
	Self-directed learning	

22. Evaluation Methods and Course Requirements:

Evaluation	Point %	Date
Midterm Exam	30	8th week
Assignments	10	3rd week
Quiz	10	11th week
Final Exam	50	16th week

23. Course Policies:

- A- Attendance policies: As per the general policy of the University of Jordan
- B- Absences from exams and handing in assignments on time: As per the general policy of the University of Jordan
- C- Health and safety procedures: N/A
- D- Honesty policy regarding cheating, plagiarism, misbehavior: As per the general policy of the University of Jordan
- E- Grading policy: See evaluation methods above
- F- Available university services that support achievement in the course:

24. Required equipment:

N/A

25. References:

- A- Required book (s), assigned reading and audio-visuals:
- 1- Pharmaceutical legislation in Jordan (The official Gazette)
 - 2- FDA Regulations
 - 3- EMEA Regulations
- B- Recommended books, materials, and media:
- 1- Pharmaceutical legislation in Jordan (The official Gazette)
 - 2- FDA Regulations
 - 3- EMEA Regulations

26. Additional information:

Name of Course Coordinator: -----Signature: ----- Date: -----

Head of curriculum committee/Department: ----- Signature: -----

Head of Department: ----- Signature: -----

Head of curriculum committee/Faculty: ----- Signature: -----

Dean: ----- -Signature: -----

Copy to:

Head of Department
Assistant Dean for Quality Assurance
Course File