

The University of Jordan

Faculty: Pharmacy

Department:

Biopharmaceutics and Clinical Pharmacy

Program: Pharmacy

Academic Year/ Semester:

2013/14 first semester

Pharmacy Regulations and Ethics (1203517)

| | | | | | |
|----------------------------------|---|--------------------------|-------------------------|----------------------|------------------------------------|
| Credit hours | 2 | Level | 2 nd year | Pre-requisite | Pharmacology (2) 1203364 |
| Coordinator/ Lecturer | | Office number | | Office phone | |
| Course website | | E-mail | | Place | |

| Office hours | | | | | |
|---------------------|---------------|---------------|----------------|------------------|-----------------|
| Day/Time | Sunday | Monday | Tuesday | Wednesday | Thursday |
| | | | | | |

Course Description

Introduction to existing laws and regulations governing the practice and ethics of pharmacy

Learning Objectives

In this course the students are expected to:

1. Demonstrate a good awareness and understanding of pharmaceutical legislation in Jordan
2. Understand the main issues of global pharmaceutical legislation

Intended Learning Outcomes (ILOs):

Successful completion of the course should lead to the following outcomes:

- 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

- 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).
- C. Subject specific skills

- 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.

ILOs: Learning and Evaluation Methods

| ILO/s | Learning Methods | Evaluation Methods |
|--|--|---------------------------------|
| A. Knowledge and Understanding B. Intellectual skills (cognitive and analytical) C. Transferable Skills: | Lectures and Discussions, Assignments Presentations | Exam, Quiz, Discussions, |
| | | |

Course Contents

| Content | Reference | Week | ILO/s |
|--|------------------|-----------------|--------------|
| <ul style="list-style-type: none"> • Introduction | | 1 st | |
| <ul style="list-style-type: none"> • An Introduction about the pharmaceutical legislation in Jordan | 1 & 2 & 3 | 1 st | A & B & D |
| <ul style="list-style-type: none"> • Medicine and pharmacy Law | 1 & 2 & 3 | 2 nd | A & B & D |
| <ul style="list-style-type: none"> • The Amended Regulations of the Accreditation Regulations of manufacturing sites: Re-evaluation, and Canceling the Accreditation rules of the year 2001 | 1 & 2 & 3 | 2 nd | A & B & D |
| <ul style="list-style-type: none"> • The Amended Regulations of the Importation and use of Medical Supplies, including: Antiseptics and Disinfectants of the year 2011 | 1 & 2 & 3 | 2 nd | A & B & D |
| <ul style="list-style-type: none"> • The Amended Regulations of pharmaceutical Registration, serums, vaccines and Biological Materials | 1 & 2 & 3 | 3 rd | A & B & D |
| <ul style="list-style-type: none"> • Regulations of Herbal Preparations and Natural | 1 & 2 & 3 | 3 rd | A & B & D |

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| Products License to the year 2011 | | | |
| <ul style="list-style-type: none"> Regulations of Preparations used in the Nuclear Medicine Regulations | 1 & 2 & 3 | 4th | A & B & D |
| <ul style="list-style-type: none"> The Regulations and Criteria Related to Pharmaceutical prices, prices Renewal, and objections against Pricing Rule to the year 2012 | 1 & 2 & 3 | 5th | A & B & D |
| <ul style="list-style-type: none"> Regulations of Pharmaceutical Preparations involving Vitamins and/or Minerals to the year 2008 | 1 & 2 & 3 | 5th | A & B & D |
| <ul style="list-style-type: none"> Regulations and Criteria of the Primary Materials of Pharmaceutical Manufacturing Control | 1 & 2 & 3 | 6th | A & B & D |
| <ul style="list-style-type: none"> Regulations of Medical Prescription | 1 & 2 & 3 | 7th | A & B & D |
| <ul style="list-style-type: none"> Regulations of considering the medicament as having Therapeutic Advantage | 1 & 2 & 3 | 8th | A & B & D |
| <ul style="list-style-type: none"> Regulations of the use of unregistered and Imported Medicaments | 1 & 2 & 3 | 9th | A & B & D |
| <ul style="list-style-type: none"> Requirements of technology transfer to | 1 & 2 & 3 | 9th | A & B & D |

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

Learning Methodology

Lectures and Discussions,

Evaluation

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

Main Reference/s:

- 1- Pharmaceutical legislation in Jordan (The official Gazette)
- 2- FDA Regulations
- 3- EMEA Regulations