**PHCL 437-Pharmacy Law and Ethics**

**CREDIT HOURS: 2+0**

**PREQUISITE: none**

**Level: 8**

**INSTRUCTORS:**

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**LEARNING OBJECTIVES**

By the end of this course students will be able to:

**Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.**

Specifically the following learning objectives are expected:

1. **Comply with governmental statutes and regulations that affect pharmacy**

**practice.**

1. **Apply principles of law to the practice of pharmacy.**
2. **Identify ethical and moral decisions faced by pharmacists during the medication distribution process.**
3. **Describe local, state, federal and international regulations affecting public health policy development.**
4. **Evaluate and resolve ethical dilemmas that arise in the development of public health**
5. **Policy or find a solution that is acceptable to all parties involved.**
6. **Describe legal and ethical implications of intervention in life threatening situations such as poisoning or drug overdose.**
7. **Demonstrate the ability to place health care and professional issues within appropriate historical, cultural, social, economic, scientific, political, and philosophical frameworks.**
8. **Display a respect and sensitivity for patient and family attitudes, behaviors and lifestyles, paying particular attention to cultural, ethnic and socioeconomic influences and incorporate cultural preferences, spiritual and health beliefs and behaviors into the patient care plan.**
9. **Use ethical principles and theories to consider alternative sides of a pharmaceutical care and/or health care dilemma.**

**COURSE OUTLINE**

|  |  |  |  |
| --- | --- | --- | --- |
| **Week** | Date | Lecture Topic | TF |
| 1 | 24 Aug.  26 Aug. | Introduction | NK |  |
|  |
| 2 | 31 Aug  2 Sep | [Institutions and Pharmaceutical Products Law](http://www.sfda.gov.sa/NR/rdonlyres/EE17CB48-AAE0-4064-B11D-2E40FCD3FE27/0/InstitutionsandPharmaceuticalProductsGuidelines.pdf) |
|  | NK |
| 3 | 7 Sep  9 Sep | Introduction to ethics in pharmacy practice |
|  | NK |
| 4 | 14 Sep  16 Sep | Pharmacy law & ethics |
| 5 | 21 SEP | HAJJ vacation | |
|  | 24 Sep |
| 6 | 27 Sep |
|  | 30 Sep |
| 7 | 5 Oct | Drugs Companies and Its Products Registration Guideline 1 | NK |
|  | 7 Oct | Midterm exam | |
| 8 | 12 oct  14 oct | Drugs Companies and Its Products Registration Guideline 2 | |
|  | Presentation part 1 | |
| 9 | 19 OCT | Presentation part 2 | |
|  | 21 OCT | Medication pricing PART 1 | EM |
| 10 | 26 OCT | Medication pricing PART 2 | EM |
|  | 28 OCT | SFDA [Regulatory Framework for Drug Approvals PART 1](http://www.sfda.gov.sa/NR/rdonlyres/2A921350-306B-4DD1-ABE0-B130558C385F/0/RegulatoryFrameworkforDrugApprovalsfinal.pdf) | EM |
| 11 | 2 Nov | SFDA [Regulatory Framework for Drug Approvals PART 2](http://www.sfda.gov.sa/NR/rdonlyres/2A921350-306B-4DD1-ABE0-B130558C385F/0/RegulatoryFrameworkforDrugApprovalsfinal.pdf) | EM |
|  | 4 NOV | Ethics and values in Pharmacy PART 1 | EM |
| 12 | 9 NOV | Ethics and values in Pharmacy PART 2 | EM |
|  | 11 Nov | Ethical Principles in pharmacy Ethics PART 1 | EM |
| 13 | 16 NOV | Ethical Principles in pharmacy Ethics PART 2 | EM |
|  | 18 Nov | Ethical issues in pharmaceutical research in Saudi Arabia PART 1 | EM |
| 14 | 23 NOV | Ethical issues in pharmaceutical research in Saudi Arabia PArT 2 | EM |
|  | 25 NOV | Ethical issues in Health education and advertisement part 1 | EM |
| 15 | 30 NOV | Ethical issues in Health education and advertisement part 2 | EM |
|  | 2 DEC | Revision and discussion | EM |

**REQUIRED READINGS:**

**A) Saudi Laws and guidelines**

1. نظام المنشاّت والمستحضرات الصيدلانية ، المملكه العربية السعوديه

و اللائحة التنفيذية لنظام المنشاّت والمستحضرات الصيدلانية، المملكه العربية السعودية

<http://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/ExecutiverolesforInstitutionsandPharmaceuticalProductslaw.pdf>

1. أسس ومتطلبات وشروط تسجيل المستحضرات الصيدلانية والعشبية وشركاتها

<http://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/أسس%20ومتطلبات%20وشروط%20تسجيل%20المستحضرات%20الصيدلانية%20والعشبية%20وشركاتها.pdf>

1. اللائحة التنفيذية لنظام المخدرات والمؤثرات العقلية

<http://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/Drugs.pdf>

1. قواعد تسعير الأدوية

[**http://www.sfda.gov.sa/ar/drug/drug\_reg/DocLib/http\_\_\_**](http://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/http___)

ام الهيئة العامة للغذاء والدواء <http://www.sfda.gov.sa/ar/Documents/ssfda.pdf>

1. نظام أخلاقيات البحث على المخلوقات الحية السعودي

<http://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/نظام_أخلاقيات_البحث_على_المخلوقات_الحية.pdf>

1. المدونةالسعوديةلأخلاقياتممارسةتسويقالمستحضراتالصيدلانيةفيالمملكةالعربيةالسعودية
2. ضوابط حملات التوعية بالأمراض والتثقيف الصحي- هيئة الغذاء والدواء السعودية

<http://www.sfda.gov.sa/ar/drug/resources/DocLib2/ضوابط_حملات_التوعية_بالامراض_والتثقيف_الصحي.pdf>

1. ضوابط المواد الترويجية التذكارية الغير دعائية- هيئة الغذاء والدواء السعودية

<http://www.sfda.gov.sa/ar/drug/resources/DocLib2/ضوابط_المواد_الترويجية_التذكارية_غير_الدعائية.pdf>

1. دليل وضوابط وإجراءات الموافقة على الدعاية أو الإعلان لمستحضر صيدلاني أو عشبي - هيئة الغذاء والدواء السعودية

<http://www.sfda.gov.sa/ar/drug/resources/DocLib2/دليل_ضوابط_وإجراءات_الموافقة_على_الدعايه_والاعلان_لمستحضر_صيدلاني_او_عشبي.pdf>

**B) Other References**

# Robert Veatch. [Amy Haddad](http://www.amazon.com/s/ref=ntt_athr_dp_sr_2?_encoding=UTF8&sort=relevancerank&search-alias=books&field-author=Amy%20Haddad). Case Studies in Pharmacy Ethics. Oxford University Press; 2 edition (2008)

1. **ACCP Position Statement. Pharmacists and industry: guidelines for ethical interactions. Pharmacotherapy 2008; 28(3):410-420.**
2. Ezekiel J. Emanuel; David Wendler; Christine Grady. W**hat makes clinical research ethical? JAMA 2000; 283(20): 2701-2711.**

# MARKS DISTRIBUTION

|  |  |
| --- | --- |
| In class activities and participation, homework and attendance | 7% |
| Professionalism | 3% |
| Presentation | 20% |
| Midterm exam | 30% |
| Final exam | 40% |
| Total | 100 |

**Presentation**

There will be a presentation on one of the topics assigned by the course coordinator.

LATE ASSIGNMENTS/HOMEWORK POLICY OR MISSED /MIDTERM EXAMS

* Late assignments/homework will be penalized by **5% reduction** in grade **per each passing day.**
* the instructor **has the right** to determine the method for midterm/quiz make up by any of the following:
  + - Increasing the percentage of the remaining exams to cover the missed exam
    - Assigning the final exam a higher percentage to cover the missed exam for the student
    - A make-up exam (mostly short note style)
    - In the final exam, the section relating to the missed examination material can be used as the grade for that missed exam.
    - Make up exam should be performed as per college policy. Valid documents about the absence MSUT be submitted by students within 2 weeks of the absence date.

ATTENDANCE POLICY:

* Students are expected to prepare for, attend and participate in all lectures and labs.
* Student must exercise **punctuality** in attending classes and labs.
* Students missing 25% or more on attendance are forbidden from setting in the final exam, per University Policy. Documents of proof ofstudent absence MUST be submitted within 2 weeks.
* A student absent from class bears full responsibility for all material covered in class. Graded activities or quizzes may be given anytime during the class period; therefore, please be on time and plan to attend the entire period. Missing an activity or a quiz due to l***ate arrivals or early departure will not be made up.***
* If you anticipate having to leave class early, please let your instructor knows before the beginning of class.
* Unprofessional conduct including misbehavior during lectures/labs will not be tolerated and may result in actions leading up to dismissal from the course.
* Mobile phone must be turned off or muted at all times during lecture and labs.

**Midterm Exams and final:** as per university schedule.