|  |  |  |
| --- | --- | --- |
| **1** | **Course title** | Pharmaceutical Regulations and Ethics |
| **2** | **Course number** | 1202517 |
| **3** | **Credit hours** | 2 (theory) |
| **Contact hours (theory, practical)** | 2 (theory) |
| **4** | **Prerequisites/corequisites** | BSc in Pharmacy and PharmD |
| **5** | **Program title** |  |
| **6** | **Program code** |  |
| **7** | **Awarding institution**  | The University of Jordan |
| **8** | **School** | Pharmacy |
| **9** | **Department** | Pharmaceutics and Pharmaceutical Technology |
| **10** | **Level of course**  | Undergraduate |
| **11** | **Year of study and semester (s)** | Second semester of the 5th year |
| **12** | **Final Qualification** | BSc in Pharmacy or PharmD |
| **13** | **Other department (s) involved in teaching the course** | NA |
| **14** | **Language of Instruction** | English |
| **15** | **Teaching methodology** | [x] Blended [x] Online |
| **16** | **Electronic platform(s)** | [x] Moodle [x] Microsoft Teams [ ] Skype [ ] Zoom [ ] Others………… |
| **17** | **Date of production/revision** | First semester 2020/2021 |

**18 Course Coordinator:**

|  |
| --- |
| **Prof. Khaled Al Fawares**Office number: Office hours:phone numbers: 23328Email address: aiedeh@ju.edu.jo |

**19 Other instructors:**

|  |
| --- |
| **Dr. Alaaldin M. Alkilany**Office number: 226Office hours:phone numbers: 23334Email address: a.alkilany@ju.edu.jo |

**20 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. |

**21 Course aims and outcomes:**

|  |
| --- |
| A- Aims:1. Provide our students with a good awareness and understanding of pharmaceutical legislation in Jordan
2. Provide our students with the main issues of global pharmaceutical legislation and codes

**B- Intended Learning Outcomes (ILOs):** **Upon successful completion of this course students should be able to:****A. Knowledge and Understanding**A1. Discuss regulations pertaining to the accreditation of manufacturing sitesA2. Discuss regulations pertaining to the importation and use of Medical Supplies, including: antiseptics and disinfectantsA3. Discuss regulations pertaining to serums-containing pharmaceutical products, vaccines and Biological Materials **B. Intellectual skills (cognitive and analytical)** B1. Recognize the differences between the various global regulationsB2. Compare Jordanian regulations to the international regulations (FDA, EMA). **C. Transferable Skills**C1. Develop of problem solving and critical thinking skills.C2. Use oral communication to effectively transmit ideas and conclusions to a scientific audience**C- Course Competencies:*** 1. Identify valid and up-to-date drug laws and regulations
	2. Characterize the national health care system and the role of the pharmacist and other healthcare
	3. professionals
	4. Identify the principles of intellectual property
	5. Abide by appropriate drug policies and regulations
	6. Ensure patient confidentiality
	7. Respect the legal rights of patients
	8. Provide patients with equal services and treatment regardless their cultural or religious differences
 |

**22. Topic Outline and Schedule:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Week** | **Lecture** | **Topic** | **Teaching Methods\*/platform** | **Evaluation Methods\*\*** |
| 1 | 1.1 | مقدمه تتضن تاريخ التشريعات الصيدلانيه في الاردن | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 1.2 | اهمية التشريعات الصيدتانيه على ممارسة المهنه | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 1.3 | NA | NA | NA |
| 2 | 2.1 | تعاريف قانونيه / قانون الدواء والصيدله رقم 12 لسنة 2013 | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 2.2 | مفهوم الدواء من ناحيه قانونيه / قانون الدواء والصيدله رقم 12 لسنة 2013 | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 2.3 |  |  | Quiz, project and Exams |
| 3 | 3.1 | دور اللجان المشكله في قانون الدواء والصيدله | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 3.2 | الاسس والمعاير القانونيه المتعلقه بالدواء | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 3.3 |  |  |  |
| 4 | 4.1 | اسس تسجيل الدواء في الاردن | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 4.2 | اسس تسعير الدواء في الاردن | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 4.3 |  |  | Quiz, project and Exams |
| 5 | 5.1 | قانونية مزاولة المهنه / قانون الدواء والصيدله | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 5.2 | تشريعات واحكام قانونيه للمؤسسات الصيدلانيه بشكل عام | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 5.3 |  |  | Quiz, project and Exams |
| 6 | 6.1 | تشريعات واحكام قانونيه للمؤسات الصيدلانيه /مصنع الادويه و مستودع الادويه | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 6.2 | تشريعات واحكام قانونيه للمؤسات الصيدلانيه / الصيدليه العامه والصيدليه الخاصه | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 6.3 |  |  | Quiz, project and Exams |
| 7 | 7.1 | احكام قانونيه / الامن الدوائي والاعلام الدوائي والتفتيش الصيدلاني | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 7.2 | قانون الدراسات الدوائيه / لمحه تاريخيه – اعلان هلسنكي لحقوق الانسان/ تعاريف قانونيه تتعلق باجراء الدراسات الدوائيه | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 7.3 |  |  |  |
| 8 | 8.1 | المواد القانونيه االمتعلقه بكيفية اجراء الدراسات الدوائيه | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 8.2 | [قانون المخدرات و المؤثرات العقلية](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D9%85%D8%AE%D8%AF%D8%B1%D8%A7%D8%AA%20%D9%88%D8%A7%D9%84%D9%85%D8%A4%D8%AB%D8%B1%D8%A7%D8%AA%20%D8%A7%D9%84%D8%B9%D9%82%D9%84%D9%8A%D8%A9.pdf) | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 8.3 |  |  | Quiz, project and Exams |
| 9 | 9.1 | [تعليمات التغيرات على الادوية المسجلة لسنة 2017](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/RegisterSection/%D8%AA%D8%B9%D9%84%D9%8A%D9%85%D8%A7%D8%AA%20%D8%A7%D9%84%D8%AA%D8%BA%D9%8A%D9%8A%D8%B1%D8%A7%D8%AA%20%D8%B9%D9%84%D9%89%20%D8%A7%D9%84%D8%A3%D8%AF%D9%88%D9%8A%D8%A9%20%D8%A7%D9%84%D9%85%D8%B3%D8%AC%D9%84%D8%A9%20%D9%84%D8%B3%D9%86%D8%A9%202017.pdf) | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 9.2 | [تعليمات التغيرات على الادوية المسجلة لسنة 2017](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/RegisterSection/%D8%AA%D8%B9%D9%84%D9%8A%D9%85%D8%A7%D8%AA%20%D8%A7%D9%84%D8%AA%D8%BA%D9%8A%D9%8A%D8%B1%D8%A7%D8%AA%20%D8%B9%D9%84%D9%89%20%D8%A7%D9%84%D8%A3%D8%AF%D9%88%D9%8A%D8%A9%20%D8%A7%D9%84%D9%85%D8%B3%D8%AC%D9%84%D8%A9%20%D9%84%D8%B3%D9%86%D8%A9%202017.pdf) | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 9.3 |  |  | Quiz, project and Exams |
| 10 | 10.1 | أسس تقييم دراسات التوافر الحيوي والتكافؤ الحيوي | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 10.2 | أسس تقييم دراسات التوافر الحيوي والتكافؤ الحيوي | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 10.3 |  |  |  |
| 11 | 11.1 | أسس تقييم دراسات التوافر الحيوي والتكافؤ الحيوي | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 11.2 | التوافر الحيوي والتكافؤ الحيوي الموضعي | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 11.3 |  |  | Quiz, project and Exams |
| 12 | 12.1 | أسس رصد الاثار الجانبية | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 12.2 | للممارسة الجيدة لتصنيع المستحضرات الصيدلانية | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 12.3 |  |  | Quiz, project and Exams |
| 13 | 13.1 | للممارسة الجيدة لتصنيع المستحضرات الصيدلانية | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 13.2 | للممارسة الجيدة لتصنيع المستحضرات الصيدلانية | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 13.3 |  |  |  |
| 14 | 14.1 | للممارسة الجيدة لتصنيع المستحضرات الصيدلانية | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 14.2 | اعتماد مواقع التصنيع 2016 | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 14.3 |  | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 15 | 15.1 | اعتماد مواقع التصنيع 2016 | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 15.2 | اعتماد مواقع التصنيع 2016 | Synchronous/Microsoft Teams | Quiz, project and Exams |
| 15.3 |  |  |  |

* Teaching methods include: Synchronous lecturing/meeting; Asynchronous lecturing/meeting
* Evaluation methods include: Quiz, project and Exams

**23 Evaluation Methods:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Opportunities to demonstrate achievement of the ILOs are provided through the following assessment methods and requirements:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Evaluation Activity** | **Mark** | **Topic(s)** | **Period (Week)** | **Platform** |
| Project  |  10 | Lectures 1.1-7.2 | Third week | Recordedvideo |
| Quiz |  10 | Lectures 1.1-7.2 |  Fifth week | Microsoft forms |
| Midterm Exam |  30 |  Lectures 1.1-7.2 |  7th week | LMS  |
| Final Exam  |  50 |  All lectures | TBA | LMS |

 |

**24 Course Requirements (e.g: students should have a computer, internet connection, webcam, account on a specific software/platform…etc):**

|  |
| --- |
| computer, internet connection, webcam, Platforms: Microsoft teams; Microsoft forms  |

**25 References:**

|  |
| --- |
| Required book(s), assigned reading and audio-visuals:**القوانين والتشريعات الخاصة بمؤسسة الغذاء والدواء والمديريات التابعة لها**<http://www.jfda.jo/Pages/viewpage.aspx?pageID=153> |

Name of Course Coordinator: ا. د. خالد الفوارس Signature: ------------------ Date: ------------

Head of Curriculum Committee/Department: ---------------------------- Signature: --------------------------

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

Head of Curriculum Committee/Faculty: ---------------------------------------- Signature: -------------------

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