

Course Plan for Bachelor Program - Study Plan Development and Updating Procedures/ Pharmacy Department	QF02/0408-4.0E
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Study Plan No.	2021/2022	University Specialization	Bachelor of Pharmacy
Course No.	0201520	Course Name	Pharmaceutical Regulatory affairs
Credit Hours	1	Prerequisite *Co-requisite	Community Pharmacy Training (2)
Course Type	☐ Mandatory University Requirement ☐ University Elective Requirement	☐ Faculty Mandatory Requirement ☐ Support course family requirements	☒ Mandatory Requirement ☐ Elective Requirement
Teaching Style	☐ Full Online Learning	☐ Blended Learning	☒ Traditional Learning
Teaching Model	☐ 1 Synchronous: 1 Asynchronous	☐ 1 Face to Face: 1 Asynchronous	☒ 1 Traditional

Faculty Member and Study Divisions Information (to be filled in each semester by the subject instructor)

Faculty Member and Study Divisions Information (to be filled in each semester by the subject instructor)					
Name	Academic rank	Office No.	Phone No.	E-mail	
Office Hours (Days/Time)					
Division number	Time	Place	Number of Students	Teaching Style	Approved Model
				Traditional Learning	1 Traditional

Brief Description

This lab is designed to give an overview of regulatory affairs profession and to impart fundamental knowledge on current international guidelines related to quality, safety and efficacy of pharmaceutical products. It reviews the current regulations related to the common technical document, process validation and stability studies.

Learning Resources

Course Book Information (Title, author, date of issue, publisher ... etc)	Quality Systems and Controls for Pharmaceuticals. Dr Dipak Kumar Sarker. John Wiley and Sons, Ltd; 2008.
Supportive Learning Resources (Books, databases, periodicals, software, applications, others)	FDA, EMEA, ICH guidelines, USP and BP.
Supporting Websites	-
The Physical Environment for Teaching	☒ Classroom ☐ Labs ☒ Virtual Educational Platform ☐ Others
Necessary Equipment and Software	Moodle
Supporting People with Special Needs	-
For Technical Support	E-Learning & Open Educational Resources Center Email: ellearning@zuj.edu.jo ; Phone: +962 6 429 1511 ext. 425/362

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Course learning outcomes (K= Knowledge, S= Skills, C= Competencies)

No.	Course Learning Outcomes	The Associated Program Learning Output Code
Knowledge		
The student should be able to:		
K1	Identify the pharmaceutical quality assurance pillars.	MK2
K2	Recognize the regulatory bodies worldwide and their guidelines	MK2
K3	Differentiate among stability studies, stability data and shelf life.	MK2
K4	Identify the requirement of process validation	MK2
Skills		
The student should be able to:		
S1	Relate stability study data to the determination of shelf life for drug substances and drug products.	MS4
S2	Construct a complete technical file for new drug registration, including all required modules and documentation.	MS4

Mechanisms for Direct Evaluation of Learning Outcomes

Type of Assessment / Learning Style	Fully Electronic Learning	Blended Learning	Traditional Learning (Theory Learning)	Traditional Learning (Practical Learning)
Midterm Exam	30%	30%	30%	0%
Participation / Practical Applications	0%	0%	0%	60%
Asynchronous Interactive Activities	30%	30%	30%	0%
Final Exam	40%	40%	40%	40%

Note 1: Asynchronous interactive activities are activities, tasks, projects, assignments, research, studies, projects, and work within student groups ... etc, which the student carries out on his own, through the virtual platform without a direct encounter with the subject teacher.

Note 2: According to the Regulations of granting Master's degree at Al-Zaytoonah University of Jordan, 40% of final evaluation goes for the final exam, and 60% for the semester work (examinations, reports, research or any scientific activity assigned to the student).

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Schedule of Simultaneous / Face-to-Face Encounters and their Topics

Week	Subject	Learning Style*	Reference ** (Pages in Course Book)
1	Introduction to regulatory affairs	participatory learning	FDA, EAMEA, ICH guidelines
2	Regulatory bodies	participatory learning	FDA, EAMEA, ICH guidelines
3	ICH guidelines	participatory learning	FDA, EAMEA, ICH guidelines
4	Introduction to quality control	participatory learning	Page 15-22
5	Quality assurance	participatory learning	Page 15-22
6	Stability testing of active substances and pharmaceutical products	participatory learning	FDA, EAMEA, ICH guidelines
7	Pharmaceutical process validation	participatory learning	Page 35-43
8	Regulations and legislation for drugs in Jordan	participatory learning	JFDA website
9	Technical dossier (eCTD)	participatory learning	FDA, EAMEA, ICH guidelines
10	Selected topics	Students' presentations	---
11	Selected topics	Students' presentations	---
12	Selected topics	Students' presentations	---
13	Selected topics	Students' presentations	---
14	Selected topics	Students' presentations	---
15	Final Exam	-	-
16	Final Exam	-	-

* Learning styles: Lecture, flipped learning, learning through projects, learning through problem solving, participatory learning ... etc.

** Reference: Pages in a book, database, recorded lecture, content on the e-learning platform, video, website ... etc.

Schedule of Asynchronous Interactive Activities (in the case of e-learning and blended learning)

Week	Task / Activity	Reference	Expected Results
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