Course Plan for Bachelor Program - Study Plan Development and Updating Procedures/ Pharmacy Department	QF02/0408-4.0E

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)*

Name	Academic rank	Office No.	Phone No.	E-mail	
Office Hours (Days/Time)	**Sunday, Tuesday, Thursday ()**		**Monday, Wednesday ()**		
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 various Good Regulatory Practices GMP, GLP and GCP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices and biological products and understand the rationale behind these requirements and ways and means of complying with them.

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: elearning@zuj.edu.jo; Phone: +962 6 429 1511 ext. 425/362

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 quality assurance pillars	**MK1**
K2	Recognize the regulatory bodies worldwide and their guidelines	**MK2**
K3	Understand the systematic drug registration process	**MK1**
Skills		
The student should be able to:		
S1	Relate the quality assurance of each pharmaceutical process with its suitable guidelines	**MS1**
S2	Structure the technical file of drugs for registration purposes	**MS1**
Competencies		
The student should be able to:		
C1	Develop the professional and individual performance by dealing with regulatory bodies	**MC1**
C1	Keep up to date with the latest regulatory guidelines	**MC1**

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%	20%	**50%**
Asynchronous Interactive Activities	20%	20%	0%	**0%**
Final Exam	50%	50%	50%	**50%**

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).*

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

Week	Subject	Learning Style*	Reference ** (Pages in Course Book)
1	Introduction to regulatory affairs	Lecture	FDA, EAMEA,ICH guidelines
2	Regulatory bodies and ICH guidelines	Lecture	FDA, EAMEA,ICH guidelines
3	Introduction to quality control and quality assurance	Lecture	Page 15-22
4	The quality assurance cycle: how quality is assessed, and who ensures quality of medicines.	Lecture	Page 15-20
5	Regulations and legislation for drugs in Jordan	Lecture	JFDA website
6	Technical dossier (eCTD)	Lecture	FDA, EAMEA,ICH guidelines
7	Pharmaceutical process validation	Lecture	Page 35-43
8	Selected topics	Students' presentations	---
	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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