

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.	0201551		Course Name		Quality Control	
Credit Hours	3		Prerequisite *Co-requisite		Pharmaceutical Technology	
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		☐ 2 Traditional	

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

Faculty Member and Study Division 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
				Blended Learning	1 Face to Face: 1 Asynchronous

Brief Description

This course is designed to discuss the basics of Good Manufacturing Practice for medicinal products for human use. It reviews the current legal regulations and guidelines, the main GMP requirements related to premises, personnel, equipment, manufacturing and packaging, documentation and validation.

Learning Resources

Course Book Information (Title, author, date of issue, publisher ... etc)	Good Manufacturing Practices for Pharmaceuticals 7 th edition by Graham P. Bunn, 2019.			
Supportive Learning Resources (Books, databases, periodicals, software, applications, others)	Quality Systems and Controls for Pharmaceuticals, by Dipak K. Sarker, 2008.			
Supporting Websites	1. U.S. FDA: CFR - Code of Federal Regulations Title 21: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211 2. Code of Federal Regulations (CFR): https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211			
The Physical Environment for Teaching	☒ Classroom	☐ Labs	☒ Virtual Educational Platform	☐ Others
Necessary Equipment and Software	Moodle			

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Supporting People with Special Needs	-
For Technical Support	E-Learning & Open Educational Resources Center Email: ellearning@zu.edu.jo ; Phone: +962 6 429 1511 ext. 291

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 Current Good Manufacturing Practices (CGMP) that includes legal and practical implications for manufacturers of medicinal products and medical devices.	MK2
K2	Recognize the general concepts of quality control, quality assurance and quality management	MK2
K3	Outline the GMP requirements related to personnel, premises, equipment, manufacturing and packaging, documentation and validation.	MK2
Skills		
The student should be able to:		
S1	Apply Good Manufacturing Practice principles to identify compliance requirements in pharmaceutical production.	MS4
S2	Evaluate Quality Management practices based on the GMP principles covered in this course.	MS4
Competencies		
The student should be able to:		

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%	30%	60%
Asynchronous Interactive Activities	30%	30%	0%	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	Lecture	Chapter 1
2	Quality Assurance and GMP	Lecture	Chapter 2
3	Quality control	Lecture	Chapter 3
4	Quality control	Lecture	Chapter 3
5	Principles of Personnel & GMP Responsibility and hygiene	Lecture	Chapter 4
6	Buildings and Facilities	Lecture	Chapter 10
7	Material management Process	Lecture	Chapter 15
8	Equipment Processing and packaging	Lecture	Chapter 11
9	Manufacturing and packaging control	Lecture	Chapter 17
10	Manufacturing and packaging control	Lecture	Chapter 17
11	Documentation and Records Standard Operating Procedures (SOP) and documentation	Lecture	Chapter 7
12	Midterm Exam	-	-
13	Documentation and Records Standard Operating Procedures (SOP) and documentation	Lecture	Chapter 7
14	Pharmaceutical validation	Lecture	Chapter 6
15	Pharmaceutical validation	Lecture	Chapter 6
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
1	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
2	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
3	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
4	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
5	Self-study	A selected topic	Assignment

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6	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
7	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
8	Self-study	A selected topic	Assignment
9	Midterm Exam	-	-
10	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
11	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
12	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
13	Self-study	A selected topic	Assignment
14	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
15	Watch a recorded lecture	Video on the E-learning platform	Answer questions embedded in the video / Assignment
16	Final Exam	-	-