

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	<input type="checkbox"/> Mandatory University Requirement <input type="checkbox"/> University Elective Requirement	<input type="checkbox"/> Faculty Mandatory Requirement <input type="checkbox"/> Support course family requirements	<input type="checkbox"/> Mandatory Requirement <input checked="" type="checkbox"/> Elective Requirement
Teaching Style	<input type="checkbox"/> Full Online Learning	<input checked="" type="checkbox"/> Blended Learning	<input type="checkbox"/> Traditional Learning
Teaching Model	<input type="checkbox"/> 1 Synchronous: 1 Asynchronous	<input checked="" type="checkbox"/> 1 Face to Face: 1 Asynchronous	<input type="checkbox"/> 2 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
				Blended Learning	1 Face to Face: 1 Asynchronous

Brief Description

This course is designed to discuss the basic and the basics of Good Manufacturing Practice for medicinal products for human use and the current legal regulations and guidelines and the main GMP requirements related to premises, storage facilities and personnel, to be familiar with the principles of the GMP quality system and quality control and the important procedures when dealing with complaints and recalls.

Learning Resources

Course Book Information (Title, author, date of issue, publisher ... etc)	Good Manufacturing Practices for Pharmaceuticals: GMP in Practice July 26, 2017, Mr B N Cooper (Author)
Supportive Learning Resources (Books, databases, periodicals, software, applications, others)	The GMP Handbook: A Guide to Quality and Compliance, by Brendan Cooper (Author), 2017
Supporting Websites	-
The Physical Environment for Teaching	<input checked="" type="checkbox"/> Classroom <input type="checkbox"/> Labs <input checked="" type="checkbox"/> Virtual Educational Platform <input type="checkbox"/> Others
Necessary Equipment and Software	Moodle
Supporting People with Special Needs	-

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For Technical Support	E-Learning & Open Educational Resources Center Email: ellearning@zuj.edu.jo ; Phone: +962 6 429 1511 ext. 291
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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 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 GMP covered in this course.	MK2
K3	Discuss the sanitation in GMP covered in this course.	MK2
K4	Outline the GMP, SOP and Deviation covered in this course.	MK2
Skills		
The student should be able to:		
S1	Overview of Good Manufacturing Practices uses.	MS4
S2	Quality Management based on the GMP covered in this course.	MS4
Competencies		
The student should be able to:		
C1	Develop his/her professional and personal performance by continuously following-up lectures, submitting tasks on time, and staying up to date with the latest Current Good Manufacturing Practices.	MC3

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).

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

Week	Subject	Learning Style*	Reference ** (Pages in Course Book)
1	Overview of Good Manufacturing Practices. Purpose and basic pharmaceutical terms	Lecture	Chapter 1
2	Quality Management	Lecture	Chapter 2
3	Principles of Personnel & GMP Responsibility and hygiene	Lecture	Chapter 3
4	Principles of Personnel & GMP Responsibility and hygiene	Lecture	Chapter 3
5	Buildings and Facilities	Lecture	Chapter 4
6	Process Equipment Processing and packaging	Lecture	Chapter 5
7	Documentation and Records Standard Operating Procedures (SOP) and documentation	Lecture	Chapter 6
8	Documentation and Records Standard Operating Procedures (SOP) and documentation	Lecture	Chapter 6
9	Materials Management Midterm Exam	Lecture	Chapter 7
10	Materials Management	Lecture	Chapter 7
11	Rejection and re-use of materials	Lecture	Chapter 8
12	Validation	Lecture	Chapter 9
13	Validation	Lecture	Chapter 9
14	Change Control	Lecture	Chapter 10
15	Complaints and recalls	Lecture	Chapter 11
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	Answer questions

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		platform	embedded in the video / Assignment
5	Self-study	A selected topic	Assignment
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	-	-