Faculty: Pharmacy	
Department: Pharmaceutics and Pharmaceutical technology	**Program:** MSc.
Semester: 1st	**Academic year:** 2024-2025

Course Plan

First: Course Information

Course Name:	Regulatory Affairs and Intellectual property			*Course No.* 1102704	
Credit Hours:	*2*	*Theoretical*	*2*	*Practical*	*NA*
Prerequisite:		*Class Number:* Section 2		*Lecture Time :* *Monday (16:30-17:30), (17:30-18:30)*	
Level in JNQF	9	*Virtual hours in the JNQF*		*80 hrs*	
Course Nature:	☐ *Mandatory Faculty Requirement* ☐ *Optional University Requirement* ☐ *Mandatory University Requirement* ☐ *Faculty Requirement* ☐ *Ancillary Course* ☐ *Optional Specialty Requirement* ■ *Mandatory Specialization requirement*				
Type of Education:	☐ Fully Face-to-Face Education ☐ Blended Education (3 Face-to-Face + 1 Asynchronous) ■ Electronic Education Fully (1 Asynchronous + 2 Synchronous)				

Second: Instructor's Information

Course coordinator:		
Name: Dr. Marwan Shalash	*Office Number: 212D*	*Email: mshalash@zu.edu.jo*
Instructor:		
Name: Dr. Marwan Shalash	*Office Number: 212D*	*Email: mshalash@zu.edu.jo*
Office Hours:	*Sunday, Monday, Tuesday, Wednesday and Thursday (10:00-11:00)*	

Third: Short Description of the Course

This course provides an in-depth exploration of the regulatory affairs in the pharmaceutical industry, focusing on standards, guidelines, development, approval, protection, and lifecycle for ensuring of pharmaceutical products safety, efficacy, and quality. Students will learn about regulatory agencies frameworks and submission requirements such as Jordan food and drug admiration (JFDA) and other global authorities , In addition, the course will explore the various aspects of intellectual property (IP) rights relevant to the pharmaceutical sector. Students will learn about IP strategy development, licensing agreements, patents, trademarks, copyrights, and trade secrets, and how these IP assets can be strategically utilized to protect innovation and secure market exclusivity. Topics include regulatory submissions, clinical trials oversight, Good Manufacturing Practices (GMP), labeling requirements, and pharmacovigilance.

By the end of this course, students will be equipped with the knowledge and skills necessary to effectively manage regulatory affairs and intellectual property matters within the pharmaceutical industry. They will be able to prepare and submit a quality regulatory dossiers, and protect their organization's intellectual property assets.

Fourth: Course objectives

1- Understand Regulatory Frameworks: To provide students a knowledge of the regulations and guidelines from major regulatory bodies (FDA, EMA, JFDA) affecting pharmaceuticals globally.

2- Learn Drug Development Processes: To teach students the stages of drug development, and the drug approval process which includes preclinical and clinical testing, Investigational New Drug Applications (IND), New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) submissions. Post-marketing surveillance, detailing the regulatory requirements, documentation, and submission processes involved. Students will learn about Good Manufacturing Practices (GMP), and the importance of regulatory compliance throughout these phases. Emphasis will be placed on understanding the required documentation and data integrity standards.

3- Develop Regulatory Submission Skills:
Prepare comprehensive regulatory submissions, including the Common Technical Document (CTD), ensuring compliance with applicable guidelines

4- Intellectual Property Fundamentals : Students will explore the fundamentals of intellectual property (IP) as it pertains to pharmaceuticals, including patents, trademarks, copyrights, and trade secrets. The course will cover how IP rights are established, maintained, and enforced in different jurisdictions.

5- Analyze Case Studies and Practical Applications
To engage in case studies and real-world examples to apply theoretical knowledge to practical scenarios and solutions in pharmaceutical regulatory affairs and intellectual property management

6- Good Regulatory Practices (GRPs):
Impart fundamental knowledge on various **Good Regulatory Practices (GRPs)** such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP) relevant to pharmaceutical production

Fifth: Learning Outcomes

Level descriptor according to (JNQF)	***CILOs Code***	***CILOs*** If any CLO will not be assessed in the course, mark NA.	***Associated PILOs Code*** *Choose one PILO for each CILO**	***Assessment method*** *Choose at least two methods*	***Scores out of 100*** State the total score identified for each CILO**	***Minimum acceptable Score/percentage (%)*** *The percentage should not be less than 50% ****
Knowledge	**K1**	Comprehend knowledge and overview of the regulatory aspects and international guidelines related to the quality, safety, and efficacy of products in the pharmaceutical industry.	**P. K2**	Final exam	20	15 (75%)
	K2	Explain the roles and regulations of various regulatory bodies, such as JFDA, FDA, and EMA, in the approval process for pharmaceuticals, medical devices, and other products, including the relevant laws, guidelines, and processes that govern product development, manufacturing, and registration.		Final exam	15	11.25 (75%)
	K3	Describe the concepts, principles, and regulations surrounding intellectual property (IP) landscapes, including patents, trademarks, copyrights, and trade secrets, as they relate to national and international laws in the pharmaceutical industry		Final exam	5	3.75 (75%)

Skills	**S1**	Practice the main regulations and guidelines for the development, manufacturing, approval, dossier submission processes of pharmaceutical products and medical devices.	**P. S2**	- Final Exam - Quizzes -Assignment	30	22.5 (75%)
	S2	Retrieve the specific regulations, laws, and guidelines for protecting intellectual property related to pharmaceutical products, including patent searches, trademarks, and trade secrets.		- Final Exam - Quizzes -Assignment	10	7.5 (75%)
Competencies	**C1**	Implement the registration process and its related aspects in pharmaceutical product development, manufacturing, and approvals, in accordance with regulations and guidelines.	**P. C2**	Assignment, Presentation	20	15 (75%)

*Refer to document (CC-2023-02) and page 2 in document (CC-2023-01)
** Refer to document (CC-2023-05)
***75% of the students** must achieve the minimal acceptable percentage or higher for each CILO

Sixth: Learning Source

Designated Book1:	**Regulatory Affairs in the Pharmaceutical Industry**	
Author: **Javed Ali, Sanjula Baboota**	***Print:*** **2022 version**	***Year:2022***
Designated Book 2:	**Basics of Regulatory Affairs for Pharma Professional**	
Author: **Dr. Jayesh Dhalani**	***Print:*** **2019**	***Year:2019***
Additional Sources: Website:	***JFDA, FDA , ICH Guidelines, GMPs, GDP and GLP Guidelines***	
Teaching Type:	***Classroom*** ☐ ***Laboratory*** ☐ ***Workshop*** ☐ **MS Teams** ■ **Moodle**	

Seventh: Course Structure

Lecture Date	Topics	Teaching Procedures*	Teaching Methods**	Covered CILOs	References*** Principles of Instrumental Analysis, Seventh Edition – By Skoog
Week 1	Overview Pharmaceutical Industry	Online	• Direct teaching • Teaching through discussion • Problem solving based teaching	K1, K2	**ICH, FDA**
Week 2	Introduction to Pharmaceutical Regulatory Affairs and global Regulatory Landscape	Online		K1, K2	**ICH, FDA**
Week 3	Drug Development Process Overview	Online		K1, K2, S1	**ICH, FDA**
Week 4	ANDA and Generic Drug Approval	Online		K1, K2, S1	**FDA**
Week 5	Regulatory Documentation and Submissions	Online		K1, K2, S1	**JFDA, FDA**
Week 6	Regulatory Documentation and Submissions	Online		K1, K2, S1, S2	**GDP, FDA**
Week 7	Global Drug Development and Harmonization	Online		K1, K2, S1	**FDA**
Week 8	JFDA and GCC requirements	Online		K1, K2, S1,C1	**JFDA**

Week 9	CTD and eCTD Submissions	Online	• Direct teaching • Teaching through discussion • Problem solving based teaching	K1, K2, S1, C1	**JFDA**
Week 10	Introduction to Intellectual Property in Pharma industry	Online		K1, K3, S2	Regulatory Affairs in the Pharmaceutical Industry
Week 11	Fundamentals of Intellectual Property in Pharma industry	Online		K2, S2	Regulatory Affairs in the Pharmaceutical Industry
Week 12	Introduction to Pharmaceutical Patent	Online		K2, S2	Regulatory Affairs in the Pharmaceutical Industry
Week 13	Pharmaceutical Patent management and strategies	Online		K2, S2, C1	Regulatory Affairs in the Pharmaceutical Industry

*Education procedures: (Direct, synchronous, asynchronous)
** Refer to document (CC-2023-04)
***Reference: Pages of the book, number of the chapter, recorded lecture, video….)

Eighth: Assessment methods

Methods	Fully Electronic Education	Blended Teaching	Direct Teaching	Specific Course Output to be measured *State the score identified for each CILO for each method of assessment out of 100 **If any CILO will not be assessed in the course, mark NA.					
				K1	K2	K3	S1	S2	C1
*Mid-term Exam									
*Final Exam	60			20	15	5	15	5	
*Quizzes	15						10	5	
*Assignment	15						5		10
* presentation	10								10
Total out of 100		100		20	15	5	30	10	20

* Refer to document (CC-2023-03)

Ninth: Course Polices

- Meeting the deadline for the lecture.
- Commitment to interaction and participation.
- Interactive lectures will be given through a platform (MS Teams).
- Duties and tests will be given through a platform (Moodle).
- Commitment to the right appearance in front of the camera with the proper background.
- University regulations for attendance and absence from lectures and examinations are in force.
- Academic Integrity: Fraud or moral impersonation are unacceptable and are punishable according to university regulations and instructions.

Approval	Name	Date	Signature
Head of Department	Dr. Randa Mansour	2024/10/07	
Faculty Dean	Dr. Ahlam Alkilani	2024/10/07