Jordan University of Science and Technology
Faculty of Pharmacy
Pharmacy Department

PHAR572 Pharmaceutical Law And Regulatory Affairs

Second Semester 2024-2025

Course Catalog
2 Credit Hours. This course provides an in-depth understanding of the regulatory environment governing pharmaceutical development, approval, and post-marketing surveillance. Emphasis is placed on the roles of regulatory agencies, regulatory submissions, Good Practices (GxPs), and international regulatory harmonization. The course prepares students to navigate regulatory frameworks to ensure the safety, efficacy, and quality of pharmaceutical products.
Teaching Method: Blended

Text Book	
Title	Fundamentals of Pharmaceutical and Biologics Regulations: A Global Perspective
Author(s)	Linda McBride and Siegfried Schmitt
Edition	4th Edition
Short Name	Ref. 1
Other Information	2023

Course References

Short name	Book name	Author(s)	Edition	Other Information
Ref. 2	Regulatory Affairs in the Pharmaceutical Industry	Javed Ali and Sanjula Baboota	1st Edition	2021

Instructor	
Name	**Dr. Mohammad Alsaggar**
Office Location	P2 L-0
Office Hours	Sun : 09:30 - 10:30 Sun : 12:00 - 13:00 Mon : 12:00 - 13:00 Tue : 12:00 - 13:00 Thu : 10:00 - 11:00 Thu : 11:00 - 12:00
Email	mhalsaggar@just.edu.jo

Class Schedule & Room
Section 1: Lecture Time: Tue : 13:00 - 15:00 Room: M3303

Prerequisites		
Line Number	**Course Name**	**Prerequisite Type**
305652	PHAR565 Pharmacoeconomics And Pharmacy Administration	Prerequisite / Study

Tentative List of Topics Covered		
Weeks	**Topic**	**References**

Week 1	Introduction to Regulatory Affairs	From **Ref. 1**, From **Ref. 2**
Week 2	Overview of Drug Development Process	From **Ref. 1**
Week 3	International Regulatory Agencies	From **Ref. 1**
Week 4	Regulatory Submission Types - IND & NDA, Generic Drugs and ANDA	From **Ref. 1**, From **Ref. 2**
Week 5	Common Technical Document (CTD) and eCTD	From **Ref. 1**
Week 6	Good Manufacturing Practice (GMP)	From **Ref. 2**
Week 7	Good Clinical and Laboratory Practices (GCP & GLP)	From **Ref. 1**
Week 8	Regulatory Affairs in Biologics, Vaccines & Biosimilars	From **Ref. 1**, From **Ref. 2**
Week 9	Pharmacovigilance and Risk Management	From **Ref. 1**
Week 10	Regulatory Affairs for Medical Devices and Combination Products	From **Ref. 1**
Week 11	Labeling, Advertising & Drug Pricing	From **Ref. 1**
Week 12	Global Harmonization and Emerging Markets	From **Ref. 1**, From **Ref. 2**
Week 13	Ethics, Data Integrity, and Regulatory Challenges	From **Ref. 1**, From **Ref. 2**
Week 14	Case Study and Student Presentation	

Mapping of Course Outcomes to Program Outcomes	**Course Outcome Weight (Out of 100%)**	**Assessment method**
Describe the structure, roles, and regulatory functions of major international health authorities (e.g., FDA, EMA, WHO) and explain their impact on pharmaceutical development and approval processes.	35%	
Interpret regulatory requirements and guidelines relevant to the preparation and submission of regulatory documents, including IND, NDA, ANDA, and CTD/eCTD dossiers.	20%	
Evaluate compliance with Good Practices (GxPs)?including GMP, GCP, and GLP?in the context of drug development, manufacturing, clinical trials, and laboratory operations.	20%	
Formulate regulatory strategies for drug lifecycle management, including risk management, pharmacovigilance, and global market authorization, considering both ethical and scientific aspects.	25%	

Relationship to Program Student Outcomes (Out of 100%)																
PLO1.1	PLO2.1	PLO3.2	PLO3.3	PLO2.2	PLO2.3	PLO2.4	PLO3.1	PLO3.4	PLO3.5	PLO3.6	PLO4.1	PLO4.2	PLO4.3	PLO4.4	PLO5.1

Evaluation	
Assessment Tool	**Weight**
Midterm Exam	45%
Active Learning	15%
Final Exam	40%

Policy	
Exams	All exams are closed book and notes. The final exam is comprehensive (covers all the material). Incomplete exams need approval from the deanship.
Cheating	Cheating is prohibited; and in case of cheating the student will be subject to punishment according to the University's regulations.
Attendance	- Excellent attendance is expected. - JUST policy requires the faculty member to assign ZERO grade (35) if a student misses 10% of the classes that are not excused. - If you miss a class, it is your responsibility to find out about any announcements or assignments you may have missed.

Date Printed: 2025-06-07