Syllabus: Pharmaceutical quality and regulatory affairs (#1917011575)
First Semester 2024 /2025

COURSE INFORMATION	
Course Name: Pharmaceutical quality and regulatory affairs **Learning method:** Blended (Live and recorded lectures) **Semester:** First **Department:** Pharmaceutics and Pharmaceutical Technology **Faculty:** Pharmaceutical Sciences	**Course Code:** 1917011575 **Section:** As per semester **Core Curriculum**: 2019 Study Plan **JNQF Level:** 7
Day(s) and Time(s): According to HU courses timetable/semester **Classroom:** As per semester **Date prepared:** June 2024 **Date updated:** November 2024	**Credit Hours:** 3 (Theory) **Prerequisites**: 131701471

COURSE DESCRIPTION

This course discusses the current applicable international guidelines and regulatory affairs related to quality, safety, and efficacy of pharmaceutical dosage forms. It also focusses on registration process, including filing, and regulatory requirements related to quality control, and quality assurance (QC/QA) regulations. A special emphasis is made in relation to stability and impurity testing. The validation process is also discussed in this course.

DELIVERY METHODS

The course will be delivered through a combination of active learning strategies. These include:
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- PowerPoint lectures and active classroom-based discussion
  Students will be encouraged to participate and be actively involved in the learning process. Lectures will start with questions to inquire about the students' prior knowledge of the topic. These questions will also be repeated at the end of the lecture to gain insight into the students' competences (to verify whether students have understood the topic). During delivering the lecture presentation, time will be given to allow students to reflect about what they have learnt and think in and discuss some examples of short case studies.
- Links to Scientific resources
- Video lectures

E-learning resources: e-reading assignments and practice clinical case studies through Microsoft Team

FACULTY INFORMATION

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Academic Title:	**Assistant Professor**
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Office Hours:	**As announced per semester** ***Please send an e-mail (idmour@hu.edu.jo) to meet at any other time.***

REFERENCES AND LEARNING RESOURCES

Required Textbook(s):.

Ansel's pharmaceutical dosage forms and drug delivery systems. Loyd V. Allen, Jr.; Nicholas G. Popovich; Howard C. Ansel. Ninth Edition, 2011

In addition to the applicable guidelines:

1. ICH guidelines, http://www.ich.org/products/guidelines.html
2. FDA guidances, https://www.fda.gov/RegulatoryInformation/Guidances/
3. EMA guidelines, http://www.ema.europa.eu/

Suggested Additional Resources:

- Rules and guidance for pharmaceutical manufacturers and distributors (The Orange Guide) 2014 - Pharmaceutical Press, London
- التشريعات الاردنية المرتبطة باجراء الدراسات الدوائية على الانسان

Useful Web Resources:

As per each lecture.

COURSE OBJECTIVES

After course completion students will be able to:

This course intends to provide the students the theoretical knowledge about the international concepts and guidelines related to manufacturing, analysis and registration of pharmaceutical products.

1. Understand and interpret regulations related to drug product registration including filing process and filing of common technical documents according to international guidelines.
2. Understand and Integrate the Good Manufacturing Practices (GMP) in the manufacturing process in the various dosage forms.
3. Develop skills related to Product development and Quality by Design (QbD)
4. Self-learn how to interpret and comply with local and international regulations related to drug product registration.
5. Identify, analyse, interpret related to QC testing

Integrate and apply knowledge related to stability and impurity testing and interpret their data

COURSE INTENDED LEARNING OUTCOMES (CILOs)

A. Knowledge and understanding

A1: Understand the basic concepts of quality (such as quality control, quality assurance and quality system) (quality risk management quality by design).

A2: Know the general guidelines related to quality, safety and efficacy of pharmaceutical products.

A3: Know the requirements for registration of a drug product filling for drug product registration including common technical document.

A4: Know the general principles of Good Manufacturing Practice (GMP) for manufacturing of Pharmaceutical dosage forms.

A5: Recognize the principle and importance of scale-up and post-approval changes guidances.

IB. ntellectual skills

B1: Perform quality risk management quality by design (QbD)

C-Approach to practice pharmacy

None.

D. Personal and professional development

D1: Develop problem solving and critical thinking skills

D2: Develop the ability to utilize IT skills in gaining and presenting information

E: Pharmaceutical Product Expert

E1: Perfrom QC testing for pharmaceutical products according to drug product specifications based on local and international guideline**s**

E2: To understand the general duties of pharmacist in registration department

ACADEMIC SUPPORT

It is The Hashemite University policy to provide educational opportunities that ensure fair, appropriate and reasonable accommodation to students who have disabilities that may affect their ability to participate in course activities or meet course requirements. Students with disabilities are encouraged to contact their instructor to ensure that their individual needs are met. The University through its Special Need section will exert all efforts to accommodate for individual's needs.

Special Needs Section:

Tel: **00962-5-3903333 Extension: 4209**
Location: **Students Affairs Deanship/ Department of Student Welfare Services**
Email: **amalomoush@hu.edu.jo**
amalomoush@staff.hu.edu.jo

COURSE REGULATIONS

Participation

Class participation and attendance are important elements of every student's learning experience at The Hashemite University, and the student is expected to attend all classes. A student should not miss more than 15% of the classes during a semester. *Those exceeding this limit of 15% will receive a failing grade regardless of their performance*. It is a student's responsibility to monitor the frequency of their own absences. **Attendance record begins on the first day of class irrespective of the period allotted to drop/add and late registration. It is a student's responsibility to sign-in; failure to do so will result in a non-attendance being recorded.**

In exceptional cases, the student, with the instructor's prior permission, could be exempted from attending a class provided that the number of such occasions does not exceed the limit allowed by the University. The instructor will determine the acceptability of an absence for being absent. A student who misses more than 25% of classes and has a valid excuse for being absent will be allowed to withdraw from the course.

On average, students need to spend 12 hrs of study and preparation weekly. At the beginning of the lectures, students should be on time and should not leave before the end of the lecture without an accepted excuse. **If the student missed a class, it is him/her responsibility to find out about any announcements or assignments they have missed.** For any clarification, students should communicate with their instructor at her posted office hours or by appointment. Students should listen well to the lecture, if anyone has a question, he/she should ask the instructor. Students can find the course material at the course Microsoft team after the lecture.

Sharing of course materials is forbidden. No course material including, but not limited to, course outline, lecture hand-outs, videos, exams, and assignments may be shared online or with anyone outside the class. Any suspected unauthorized sharing of materials, will be reported to the university's Legal Affairs Office. If a student violates this restriction, it could lead to student misconduct procedures.

Plagiarism
Plagiarism is considered a serious academic offence and can result in your work losing marks or being failed. HU expects its students to adopt and abide by the highest standards of conduct in their interaction with their professors, peers, and the wider University community. As such, a student is expected not to engage in behaviours that compromise his/her own integrity as well as that of The Hashemite University.

Plagiarism includes the following examples, and it applies to all student assignments or submitted work:

- **Use of the work, ideas, images or words of someone else without his/her permission or reference to them.**
- **Use of someone else's wording, name, phrase, sentence, paragraph or essay without using quotation marks.**
- **Misrepresentation of the sources that were used.**

<u>The instructor has the right to fail the coursework or deduct marks where plagiarism is detected</u>

Missed Assessments
In all cases of assessment, students who fails to attend an exam on the scheduled date without prior permission, and/or are unable to provide a medical note, will automatically receive a failure grade for this part of the assessment.

In cases where a student misses an assessment on account of a medical reason or with prior permission; in line with university regulations an incomplete grade for the specific assessment will be awarded and an alternative assessment or extension can be arranged.

Cheating
Cheating, academic disconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied. Cheating policy: The participation, the commitment of cheating will lead to applying all following penalties together:

- Failing the subject, he/she cheated at
- Failing the other subjects taken in the same course
- Not allowed to register for the next semester
- The summer semester is not considered as a semester

Student Complaints Policy
Students at The Hashemite University have the right to pursue complaints related to faculty, staff, and other students. The nature of the complaints may be either academic or non-academic. For more information about the policy and processes related to this policy, you may refer to the students' handbook.

COURSE ASSESSMENT

Course Calendar and Assessment

Students will be graded through the following means of assessment:

Course Assessment Plan							
Assessment	**Grade Weighting**	**Deadline Assessment**	**CILOs**				
			A	**B**	**C**		
First Exam	30%	~ 6th week	A	B	C	D	E
Second Exam	30%	~ 10th week	A	B	C	D	E
Final Exam	40%	~ 15th /16th week	A	B	C	D	E

Description of Exams

Test questions will predominately come from material presented in the lectures and the lectures themselves. Semester exams may be conducted during the regularly scheduled lecture period. Exam may consist of a combination of multiple choice, short answer, match, true and false, and/or descriptive questions.

No make-up exams will be given. Only documented absences will be considered as per HU guidelines. Make-up exams may be different from regular exams in content and format.

Grades are not negotiable and are awarded according to the following criteria:

Letter Grade	Description	Grade Points
A+	Excellent	4.00
A		3.75
A-		3.50
B+	Very Good	3.25
B		3.00
B-		2.75
C+	Good	2.50
C		2.25
C-		2.00
D+	Pass	1.75
D	Pass	1.50
F	Fail	0.00
I	Incomplete	-

WEEKLY LECTURE SCHEDULE AND CONTENT DISTRIBUTION

"Lecture hours and weeks are approximate and may change as needed"

Note: For the 2 lecture periods per week (S/T, M/W), one lecture period covers one and half an hour lecture (75 minutes). The course content specifies chapters of the textbook that will be included in exams.

All lectures are delivered by face-to-face learning and recorded lectures

Course Content					
Week Number	**No. of Hours**	**CILOs**	**Subject**	**Delivery Methods**	**Assessment Methods**
١	**1-2**	A,B	**Introduction** • What is Quality? • Quality system • Regulatory authorities and pharmacopeias • International harmonization and collaboration platforms **New drug development and approval process**	Active Classroom-Based Discussions	Exams
2	**3-4**	A	**Electronic CTD : The common technical document for the registration of pharmaceuticals for human use** • What is (common technical document) CTD? • Advantages of CTD • Organization of CTD	PowerPoint Lecture Active Classroom-Based Discussions Relevant Videos	Exams
3-4	**5-7**	A, D	• **Specifications: test procedures and acceptance criteria for new drug substances and new drug products: chemical substances** • **Lecture** • Definitions • Specifications and acceptance criteria • General concepts • Periodic or Skip Testing • Release vs. Shelf-life Acceptance Criteria • In-process Tests • Limited Data Available at Filing • Parametric Release • Alternative Procedures • Guidelines • Universal & Specific Tests / Criteria : New Drug Substances • Universal & Specific Tests / Criteria : New	PowerPoint Lecture Active Classroom-Based Discussions Relevant Videos	Exams

			Drug products		
5-6	**8-10**	D,E	**Impurities in new drug substances and drug products** • Classification of impurities • Rationale for the reporting and control of impurities • Qualification of impurities • Reporting impurity content of batches • Listing of impurities in specifications • Classification of residual solvents by risk assessment • Limits of residual solvents • Safety assessment of potential elemental impurities • Element classification • Risk assessment and control of elemental impurities	PowerPoint Lecture Active Classroom-Based Discussions Relevant Videos	Exams
7-8	**11-13**	D,E	**Stability testing of new drug substances and products** • Stress Testing • Selection of Batches • Testing Frequency • Storage Conditions • Stability Commitment • Evaluation for stability data	PowerPoint Lecture Active Classroom-Based Discussions Relevant Videos	Exams
Week 9-10	**14-16**	A	**Good Manufacturing Practices (GMPs)** • Pharmaceutical quality system • Personnel • Premises and equipment • Documentation • Production • Quality control • Outsourced activities • Complaints and product recall Self-inspection	PowerPoint Lecture Active Classroom-Based Discussions Relevant Videos	Exams
11	**17-18**	C,D	**Validation of analytical procedures**	Active Classroom-	Exams

			• What is validation? • Qualification vs. validation • Validation master plan • Process validation • Types of validation • Cleaning validation Validation of analytical procedures	Based Discussions Relevant Videos	
12	**19-20**	D,E	**Product development , Quality by Design , and quality risk management** • Introduction • QbD elements • Process Analytical Technology • General quality risk management process Risk management methodology	Active Classroom-Based Discussions Relevant Videos	Exams
13-14	**21-23**	D,E	**Special topics Coducting clincial trials** • **Bioavalibility and bioequivalence studies (BA and BE Practical issues)** • Design, conduct and evaluation of BA and BE studies • Clinical study report • BCS-based biowaiver • **Quality control (Practical issues)** • Data interpretation for QC for Solid dosage forms In vitro dissolution tests	Active Classroom-Based Discussions Relevant Videos	Exams
١٥	-	A, B, C, D	**University Final Exams**		Exams