**The Hashemite University**

الجامعـــــــــة
الهاشميـــــــــة

**Faculty of Pharmaceutical Sciences**

# Syllabus: Pharmaceutical quality and regulatory affairs (131701575)
# First Semester 2021 /2022

| COURSE INFORMATION | |
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| **Course Name:** Pharmaceutical quality and regulatory affairs (face-to-face+online learning)<br>**Semester:**First<br>**Department:**Department of Department of Pharmaceutics and Pharmaceutical Technology<br>**Faculty:** Pharmaceutical Sciences | **Course Code:** 131701333<br>**Section:**<br>**Core Curriculum**: Compulsory |
| **Day(s) and Time(s):** :<br>Sun, Mon, Tues: TBA<br>Mon, Wed: TBA<br>**Classroom: TBA** | **Credit Hours:** 2<br>**Prerequisites**: Industrial Pharmacy (2) (131701471) |

## COURSE DESCRIPTION

This course investigates the current international guidelines and regulatory affairs related to the quality, safety, and efficacy of pharmaceutical dosage forms. It reviews the different guidelines related to the common technical document, test procedures and acceptance criteria for new drug substances and new drug products, Impurities in new drug substances and drug products, stability testing of new drug substances and products, Good Manufacturing Practices, Scale-Up and Postapproval Changes (SUPAC) Regulations, validation of analytical procedures, product development, Quality by Design and quality risk management, and investigation of bioequivalence studies.

## DELIVERY METHODS

The course will be delivered through a combination of active learning strategies. These will include:

- PowerPoint lectures and active classroom-based discussion
- Collaborative learning through small groups acting in an interdisciplinary context.
- E-learning resources: e-reading assignments and practice quizzes through Model and Microsoft Team
- Videos
- Websites related to the guidelines

## FACULTY INFORMATION

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| **Name** | **Dr.Areen Sulaiman Alshweiat** |
| **Academic Title:** | **Assistant Professor** |
| **Office Location:** | **A429** |
| **Telephone Number:** | **3429** |
| **Email Address:** | **Areen.alshweiat@hu.edu.jo** |
| **Office Hours:** | **TBA**<br>*Please send an e-mail ( Areen.alshweiat@hu.edu.jo) to meet at any other time.* |

## REFERENCES AND LEARNING RESOURCES

**Required Textbook**

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

**Suggested Additional Resources**:

1. Rules and guidance for pharmaceutical manufacturers and distributors (The Orange Guide).
2. Ansel's pharmaceutical dosage forms and drug delivery systems. Loyd V. Allen, Jr.; Nicholas G. Popovich; Howard C. Ansel. Ninth Edition, 2011.

## STUDENT LEARNING OUTCOMES MATRIX*

| Core Curriculum Learning Outcomes | Program Learning Outcomes | Course Objectives | Course Student Learning Outcomes | Assessment Method |
|---|---|---|---|---|
| CLO-1<br>Knowledge and understanding | | 1. Understand the basic concepts of quality (such as quality control, quality assurance, quality system, quality risk management and quality by design). | 1.1. Understand the rationale of the international concepts and guidelines related to manufacturing, analysis and registration of pharmaceutical products. | • Exams<br>• Quizzes<br>• homework assignments<br>• Project |
| | | 2. Know the general guidelines related to quality, safety and efficacy of pharmaceutical products. | 2.1. Understand the general guidelines related to the pharmaceutical products. | • Exams<br>• Quizzes |
| | | 3. Know the requirements for registration of a drug product. | 3.1. Understand the methods to file an application for drug substance and drug product registration. | • Exams<br>• Quizzes<br>• Homework assignments |
| | | 4. Know the design of common technical document | 4.1. Know the content of the common technical document | • Exams<br>• Quizzes<br>• Homework assignments |
| | | 5. Understand the principles for setting specifications for new drug substances and new drug products | 5.1. Know all methods for the universal and specific specification of the products. | • Exams<br>• Project<br>• Homework assignments |
| | | 6. know the general principles of Good Manufacturing Practice (GMP) for manufacturing of Pharmaceutical dosage forms | 6.1. Understand the requirements of the GMP and learn how to select the plant's design based on these requirements.<br>6.2. Able to make decision related for design, units responsibilities, complaints, and auditing based on the GMP requirements. | • Exams<br>• Project<br>• Homework assignments |
| | | 7. Recognize the principle and importance of scale-up and post-approval changes guidance. | 7.1. Able to identify the level of changes and make decision related for changes and scale-up after getting the approval. | • Exams<br>• Project<br>• Homework assignments |

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| | | 8. Recognize the principle and importance of analytical procedure validation | 8.1.Identify the requirement of process validation and how to express the validation parameter. | • Exams<br>• Project<br>• Homework assignments |
| | | 9. understand the quality by design (QbD) system. | 9.1. Identify the elements of the QbD and its important to achieve the required quality of pharmaceutical products. | • Exams<br>• Project<br>• Homework assignments |
| CLO-2 Intellectual skills | 2: Use modern literature search methods and guidelines to obtain information about the specification and tests for drug substance and drug product | 1. To be able to set and justify specifications based on international guidelines. | 1.1. Acquire the ability to learn how to justify the test, missing of the test, or changing the tests. | • "On-line" reading assignments<br>• Term project |
| | | 2. To be able to set and justify shelf life based on stability data | 2.1. Acquire the ability to do the stability studies and learn about the requirements of these studies based on the type of the drug substance and drug product.<br>2.2. Learn to justify the test,<br>2.3. Learn to connect between the stability studies and shelf life for the different drug substance and drug product. | • Exams<br>• "On-line" reading assignments<br>• Term project |
| CLO-3 Personal and professional development | 3: To develop critical thinking, problem solving and decision making abilities | 1.To be able to present the justification for required test and the approval or rejection decision of drug substance and drug product. | 1.1. Develop problem solving and critical thinking skills.<br>1.2. Develop the ability to utilize IT skills in gaining and presenting information<br>1.3. Develop skills of team work and time management | • Exams<br>• "On-line" reading assignments<br>• Term project |

## 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.

**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 15 hrs of study and preparation weekly. At the beginning of the lectures, be on time and don't leave before the end of the lecture without an accepted excuse. If you missed a class, it is your responsibility to find out about any announcements or assignments you have missed. For any clarification, please communicate your instructor at her posted office hours or by appointment. Listen well to the lecture, if you have a question, ask your instructor. You will find the course material at the course team after the lecture.

***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.**

**The instructor has the right to fail the coursework or deduct marks where plagiarism is detected**

***Late or Missed Assignments***

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

- Submitting a term paper on time is a key part of the assessment process. Students who fail to submit their work by the deadline specified will automatically receive a 10% penalty. Assignments handed in more than 24 hours late will receive a further 10% penalty. Each subsequent 24 hours will result in a further 10% penalty.
- 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.

***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 and their final grade will be calculated from the forms of assessment as listed below with their grade weighting taken into account. The criteria for grading are listed at the end of the syllabus

| Assessment | Grade Weighting | Deadline Assessment |
|---|---|---|
| First exam | 25% | TBA |
| Second exam | 25% | TBA |
| Quizzes-Homework | 10% | TBA |
| Final exam | 40% | TBA |

**Description of Exams**

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

**Homework:** Will be given for the selected chapters, while the chapter in progress you are supposed to work on them continuously and submit in the announced date.

You are also expected to work on in-chapter examples, self-tests and representative number of end of chapter problems. The answers of self-tests and end of chapter exercises are given at the end of the book.

**Quizzes:** Announced quizzes will be given during or/and at the end of each chapter based upon the previous lectures.

No make-up exams, homework or quizzes will be given. Only documented absences will be considered as per HU guidelines.

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

Note: For Physical Pharmacy 2 sections with 2 lecture periods per week (S/T or M/W ), one lecture period covers 1.5 lecture hours (80 minutes). The course content specifies the sections in chapters of the reference textbooks will be included in quizzes, homework and exams.

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| **ICH Q9,Q10 Introduction Week 1 2 lecture hours** |
| **What is Quality?** |
| **Quality system** |
| **Regulatory authorities and pharmacopeias** |
| **International harmonization and collaboration platforms** |
| **New drug development and approval process** |
| **What is Quality?** |
| **Quality system** |
| ***M4*** **The common technical document for the registration of pharmaceuticals for human use Week 2 2 lecture hours** |
| **What is (common technical document) CTD?** |
| **Advantages of CTD** |
| **Organization of CTD** |
| **Electronic CTD** |
| ***ICH Q6A*** **Specifications: test procedures and acceptance criteria for new drug substances and new drug proc chemical substances Week 3-4 3 lecture hours** |
| **Definitions** |

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|---|---|---|---|
| **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** | | | |
| ***ICH Q3A, Q3B, Q3C, Q3D*** | **Impurities in new drug substances and drug products** | **Week 4-5** | **3 le hours** |
| **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** | | | |
| **Safety assessment of potential elemental impurities** | | | |
| **Element classification** | | | |
| **Risk assessment and control of elemental impurities** | | | |
| ***ICH Q1A*** | **Stability testing of new drug substances and products** | **Week 5-6** | **3 lecture hours** |
| **Stress Testing** | | | |
| **Selection of Batches** | | | |
| **Testing Frequency** | | | |
| **Storage Conditions** | | | |
| **Stability Commitment** | | | |
| **Evaluation for stability data** | | | |
| ***FDA guidances*** | **Good Manufacturing Practices (GMPs)** | **Week 6-9** | **6 lecture hours** |
| **Pharmaceutical quality system** | | | |
| **Personnel** | | | |
| **Premises and equipment** | | | |
| **Documentation** | | | |
| **Production** | | | |
| **Quality control** | | | |
| **Outsourced activities** | | | |
| **Complaints and product recall** | | | |
| **Self-inspection** | | | |
| ***FDA*** | **Scale-Up and Postapproval Changes (SUPAC) Regulations** | **Week 9-10** | **2 lecture hours** |
| **What is SUPAC?** | | | |
| **Rationale of SUPAC guidelines** | | | |
| **Levels of changes** | | | |
| **What is SUPAC?** | | | |
| **Rationale of SUPAC guidelines** | | | |
| ***ICH Q2(R1)*** | **Validation of analytical procedures** | **Week 10-11** | **2 lecture hours** |
| **What is validation?** | | | |
| **Qualification vs. validation** | | | |
| **Validation master plan** | | | |

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| ***ICH Q8(R2), Q9*** **Product development , Quality by Design , and quality risk management** | | **Week 11-12** | **3 lectur hours** |
| **Introduction** | | | |
| **QbD elements** | | | |
| **Process Analytical Technology** | | | |
| ***FDA, EMA*** **Guideline on the investigation of bioequivalence** | **Week 12-14** | **3 lecture hours** | |
| **Design, conduct and evaluation of bioequivalence studies** | | | |
| **In vitro dissolution tests** | | | |
| **Bioequivalence study report** | | | |
| **BCS-based biowaiver** | | | |
| ***Review*** | | ***Week 15*** | |
| **University Exams** | | ***Week 16*** | |

## ASSESSMENT RUBRICS

| Classroom Participation: Assessment Criteria | | | | | |
|---|---|---|---|---|---|
| **Criteria** | **Quality** | | | | **Score** |
| | **Excellent (4 points)** | **Good (3 points)** | **Satisfactory (2 points)** | **Needs Improvement (1 points)** | |
| **Degree to which student integrates course readings into classroom participation** | - often cites from readings;<br>- uses readings to support points;<br>- often articulates "fit" of readings with topic at hand. | -occasionally cites from readings;<br>- sometimes uses readings to support points;<br>-occasionally articulates "fit" of readings with topic at hand . | -rarely able to cite from readings;<br>- rarely uses readings to support points;<br>- rarely articulates "fit" of readings with topic at hand | -unable to cite from readings;<br>-cannot use readings to support points; cannot articulates "fit" of readings with topic at hand . | |
| **Interaction / participation in classroom discussions** | -always a willing participant, responds frequently to questions;<br>- routinely volunteers point of view . | -often a willing participant,<br>- responds occasionally to questions;<br>- occasionally volunteers point of view . | -rarely a willing participant,<br>- rarely able to respond to questions;<br>- rarely volunteers point of view . | -never a willing participant.,<br>- never able to respond to questions;<br>- never volunteers point of view . | |
| **Interaction /participation in classroom learning activities** | -always a willing participant;<br>-acts appropriately during all role plays;<br>- responds frequently to questions;<br>- routinely volunteers point of view. | -often a willing participant;<br>-acts appropriately during role plays;<br>- responds occasionally to questions;<br>-occasionally volunteers point of view. | -rarely a willing participant.<br>-occasionally acts inappropriately during role plays;<br>- rarely able to respond to direct questions;<br>-rarely volunteers point of view . | -never a willing participant<br>- often acts inappropriately during role plays;,<br>- never able to respond to direct questions;<br>- never volunteers point of view. | |
| **Demonstration of professional attitude and demeanor** | -always demonstrates commitment through thorough preparation;<br>- always arrives on time;<br>- often solicits instructors' perspective outside class. | - rarely unprepared; rarely arrives late;<br>- occasionally solicits instructors' perspective outside class . | -often unprepared; occasionally arrives late;<br>- rarely solicits instructors' perspective outside class . | -rarely prepared;<br>- often arrives late;<br>-never solicits instructors' perspective outside class | |

| *Classroom Participation: Oral Presentation* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Element** | **Excellent** | | | **Satisfactory** | | | **Needs Improvement** | | | **Points** |
| | **8** | **7** | **6** | **5** | **4** | **3** | **2** | **1** | **0** | |
| **Organization** | ▪ There is a logical sequence of information.<br>▪ Title slide and closing slide are included appropriately. | | | ▪ There is some logical sequence of information.<br>▪ Title slide and closing slides are included. | | | ▪ There is little or no logical sequence of information.<br>▪ Title slide and/ or closing slides are not included. | | | |
| **Slide Design** (text, colors, background, illustrations, size, titles, subtitles) | ▪ Presentation is attractive and appealing to viewers. | | | ▪ Presentation is somewhat appealing to viewers. | | | ▪ Little to no attempt has been made to make presentation appealing to viewers. | | | |
| **Content** | ▪ Presentation covers topic completely and in depth.<br>▪ Information is clear, appropriate, and accurate. | | | ▪ Presentation includes some essential information.<br>▪ Some information is somewhat confusing, incorrect, or flawed. | | | ▪ Presentation includes little essential information.<br>▪ Information is confusing, inaccurate, or flawed. | | | |
| **Language** | ▪ Spelling, grammar, usage, and punctuation are accurate<br>▪ Fluent and effective | | | ▪ There are minor problems in spelling, grammar, usage, and/or punctuation. | | | ▪ There are persistent errors in spelling, grammar, usage, and/or punctuation.<br>▪ Less or not fluent and effective. | | | |
| **Delivery** | ▪ Ideas were communicated with enthusiasm, proper voice projection and clear delivery.<br>▪ There was sufficient eye contact with audience.<br>▪ There were sufficient use of other non-verbal communication skills. | | | ▪ There was some difficulty communicating ideas due to voice projection, lack of preparation, incomplete work, and/or insufficient eye contact.<br>▪ Insufficient use of non-verbal communication skills.<br>▪ Delivery pace is somewhat appropriate. | | | ▪ There was great difficulty communicating ideas due to poor voice projection, lack of preparation, incomplete work, and/or little or no eye contact.<br>▪ No use of non verbal communication skills. | | | |

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| | ▪ Appropriate delivery pace was used. | | ▪ Inappropriate delivery pace was used. | |
| **Interaction with Audience** | ▪ Answers to questions are coherent and complete.<br><br>▪ Answers demonstrate confidence and extensive knowledge. | ▪ Most answers to questions are coherent and complete.<br><br>▪ Answers somehow demonstrate confidence and extensive knowledge. | ▪ Answers to questions are neither coherent nor complete.<br><br>▪ Is tentative or unclear in responses. | |
| | **Total Score (Y x 5/16 ) =** | | | |