Philadelphia University
Faculty of Pharmacy
First Semester, 2021/2022
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اسم النموذج : خطة المادة الدراسية	**رمز النموذج :**	QFO-AP-VA-008
الجهة المصدرة: نائب الرئيس للشؤون الأكاديمية	**رقم الإصدار: (Rev)**	2
الجهة المدققة : اللجنة العليا لضمان الجودة	**تاريخ الإصدار:**	2021-5-4
	عدد صفحات النموذج :	4

جامعة فيلادلفيا
Philadelphia University

Course syllabus	
Course title: Pharmaceutical quality control and assurance	**Course code: 0510525**
Course level: Senior	**Course prerequisite: 0510323**
Lecture time 12:45- 14:00 (M, W)	**Credit hours: 3**
	Contact hours: 3

Academic Staff Specifics

Name	Rank	Office number and location	Office hours	E-mail address
Abdulmuttaleb Jaber	**Professor**	**09210**	**11:00-12:00 (M, W)**	**ajaber@philadelphia.edu.jo**

Course description (According to the University Catalogue)
This course deals with the quality assurance programs applied in pharmaceutical practice and validation of these programs. Discuss the Practical experience in quality control through skills gained in areas such as raw material testing, in-process testing, finished product testing, method and instrumental validation, process Validation, drug stability, pharmaceutical statistics, quality control charts, process capability analysis, acceptance sampling plans and cGMP/GLP Compliance. Quality management systems and standards such as TQM, ISO, GMP is also included.

Course objectives
- Introduce students to fundamental concepts of quality assurance, quality control, quality management, total quality system, validation, good manufacturing practice, regulatory affairs quality system and other relevant concepts.
- Discuss some aspects (concepts, tests and control charts) of statistical treatments of analytical data pertinent to the pharmaceutical analysis.
- Provide students with the awareness on how industry professionals and practicing pharmacists access the compliance information used routinely in pharmaceutical industry.

- Introduce students to selected laws and regulations pertaining to the development and approval of drugs, and make them aware of the good drug regulatory practices concept.
- Discuss the main aspects of good manufacturing practice, GMP.

Course learning outcomes

At the end of the course the students are expected to develop the following knowledge and skills:

A: Knowledge

A1: Describe the basic principles and define the common terms pertinent to quality in pharmaceutical industry.

A2: Discuss the statistical terms and tests used for treatment of pharmaceutical analytical data.

A3: Recognize the concept of validation/qualification pertinent to the manufacturing of pharmaceutical products

A4: Describe the experimental protocols for conducting the various validation parameters in the pharmaceutical quality control laboratories.

A5: Demonstrate knowledge pertinent to good manufacturing practice, regulatory affairs, pharmaceutical dossiers and drug stability.

B: Skills

B1: Express knowledge pertinent to the background, role and purpose of quality programs in the pharmaceutical industry.

B2: Apply various statistical terms and tests used for emphasizing QA and QC in pharmaceutical industry.

B3: Prepare documents pertinent to quality management such as validation, quality manual, Pharmaceutical dossier and others.

B4: Demonstrate ability to search and use the chemical literature in both printed and electronic formats.

B5: Demonstrate effective written and oral communication skills, especially the ability to transmit complex technical information in a clear and concise manner.

C: Competencies

C1: Demonstrate capability in using various statistical terms, statistical tests and control charts used for treatment of pharmaceutical analytical data.

C2: Acquire all the skills required in the validation of analytical methods used in the pharmaceutical quality control laboratories.

C3: Possess the background to work with the pharmaceutical agencies as a regulatory affairs officer and to prepare the pharmaceutical dossier needed for the drug registration.

C4: Demonstrate capability in using GMP guidelines to develop processes, procedures, training and documentation to produce pharmaceuticals of appropriate quality and quality assures them.

C5: Utilize skills and knowledge that help in gaining employment in the regulated pharmaceutical industry.

Course resources

1. Dipak K. Sarker, Quality Systems and Controls for Pharmaceuticals, John Wiley & Sons Ltd, 2008.
2. Joseph D. Nally. Editor, Good Manufacturing Practices for Pharmaceuticals, Informa Healthcare USA, Inc, 2007.
3. D. Brynn Hibbert, Quality Assurance for the Analytical Chemistry Laboratory, Oxford University Press, 2007.
4. Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011.
5. Helene I. Dumitriu, Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual, Informa healthcare, 1997.

6. World Health Organization Quality assurance of pharmaceuticals: A compendium of guidelines and related materials, Volume 2, 2nd ed. 2007.
7. Douglas J. Pisano and David Mantus (Editors), FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, CRC Press, 2004.
8. Syed Imtiaz Haider, Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance, A CRC Press Company, London, 2001.
9. Shyne Cox Gad, Editor, Pharmaceutical manufacturing handbook: Regulations and Quality, John Wiley and Sons, 2008.

- **Support materials**
  Handouts pertinent to all topics from the different textbooks will be provided. Besides, all presentations will be posted on the University Website.

- **Homework and laboratory guide (s) if (applicable).**
  Case studies or numerical problems will be assigned to students to be posted under assignments on the Moodle Platform.

Teaching methods

In class lecturing where current topics are interrelated to the past and future topics will be discussed. Some case studies and numerical examples will be presented in the classes whenever it is applicable.

Assessment instruments

- Exams (Midterm and Final Exams)
- Quizzes.
- Homework assignments

Allocation of Marks	
Assessment Instruments	**Mark**
Midterm Exam	**30**
Quizzes and other assignments	**30**
Final Exam	**40**
Total	**100**

Documentation and academic honesty

- ***Documentation style (with illustrative examples)***

Whenever applicable, students should conduct their assignments themselves whether individually or in a group work referencing all information, data, figures and diagrams taken from literature. The references should be given according to the acceptable format.

- ***Protection by copyright***

Students should realize that some published information or data are the property of their authors and they are not allowed to use it without asking permission from the originators.

- ***Avoiding plagiarism.***

Plagiarism is the unauthorized use or close imitation of the language and thoughts of another author and the representation of them as one's own original work, without proper acknowledgment of the author or the source. Students must pursue their studies honestly and ethically in accordance with the academic regulations. Cheating in exams and plagiarism are totally unacceptable and those who, intentionally, commit such acts would be subjected for penalties according to the University regulations.

Topical outline and tentative schedule

1. All material to be covered is drawn from the books indicated in the Table.
2. Teaching methodology will be mainly in-class lecturing.
3. Homework assignments will be given throughout the Philadelphia University Moodle Platform. Students should submit their homework assignments on the Moodle Platform.

Week #/ Date/ /Lecture #	Topics to be covered	Source	Homework
Week #1: 17-21/10/21 Lectures 1 & 2	Introduction to Quality: Definitions, and Introduction to Quality in the Analytical Chemistry Laboratory	Handouts and (Chapters 1& 2) (pp. 3-22) (D. Brynn Hibbert, Quality Assurance for the Analytical Chemistry Laboratory, Oxford University Press, 2007).	-
Week #2: 24-28/10/21 Lectures 3 & 4	Introduction to Quality: Definitions, and Introduction to Quality in the Analytical Chemistry Laboratory	Handouts and (Chapters 1 & 2) (pp. 3-22) (D. Brynn Hibbert, Quality Assurance for the Analytical Chemistry Laboratory, Oxford University Press, 2007)	-
Week #3: 31/10-4/11/2 Lectures 5 & 6	Types of Errors in Instrumental Analysis	(Chapter 3) (pp 7-35). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011)	Selected questions will be assigned
Week #4: 7-11/11/21 Lectures 7 & 8	Types of Errors in Instrumental Analysis	(Chapter 3) (pp 7-35). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011).	Selected questions will be assigned
Week #5: 14-18/11/21 Lectures 9 & 10	Statistical Tests	(Chapter 4) (pp. 37-77). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011)	Selected questions will be assigned.
Week #6: 21-25/11/21 Lectures 11 & 12	Control Charts in the Analytical Laboratory	(Chapter 5) (pp287-304). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011)	Selected questions will be assigned
Week #7: 28/11-02/12/21 Lectures 13 & 14	Validation of Method Performance in pharmaceutical analysis	(Chapter 6) (pp. 79-116). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011)	Selected questions will be assigned
Week #8: 5-9/12/21 Lectures 15 & 16	Validation of Method Performance in pharmaceutical analysis	(Chapter 6) (pp. 79-116). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011)	Selected questions will be assigned
Week #8: 12-16/12/21 Lectures 15 & 16	Validation of Method Performance in pharmaceutical analysis	(Chapter 6) (pp. 79-116). (Manfred Reichenba¨cher, Ju¨rgen W. Einax , Challenges in Analytical Quality Assurance, Springer, 2011)	Selected questions will be assigned
Week # 10	**Second Exam.** **To be announced**	All material covered	

Week #/ Date/ /Lecture #	Topics to be covered	Source	Homework
Week #10: 19-23/12/21 Lectures 19 & 20	Good manufacturing practices	Chapter 7 (pp. 57-96).	Selected questions will be assigned
Week #11: 26-30/12/21 Lectures 21& 22	Good manufacturing practices	Chapter 7 (pp. 57-96)	Selected questions will be assigned
Week #12: 2-6/1/22 Lectures 23 & 24	The Regulatory Affairs Quality System: Historical overview	Chapter 8 Part I (pp. 3-44). (Helene I. Dumitriu, GOOD DRUG REGULATORY PRACTICES: A Regulatory Affairs Quality Manual, informa healthcare, 1997)	-
Week #13: 9-13/1/22 Lectures 25 & 26	Drug stability	Section 9 (pp. 557-701) (Shyne Cox Gad, Pharmaceutical manufacturing handbook: Regulations and Quality, John Wiley & Sons Ltd, 2008)	-
Week #14: 16-20/12/22 Lectures 27 & 28	Overview of Drug Development and the FDA	Chapter 10 (pp. 8-20) (Douglas J. Pisano and David Mantus (Editors), FDA REGULATORY AFFAIRS: A Guide for Prescription Drugs, Medical Devices, and Biologics, CRC Press, 2004)	-
Week #15: 23-27/1/22 Lectures 29 & 30	Applications of QA to new medicinal products and new chemical entities formulation	Chapter 11 (pp. 119—133-136) (Dipak K. Sarker, Quality Systems and Controls for Pharmaceuticals, John Wiley & Sons Ltd, 2008)	-
Week #16: 30/1-3/2/22 **Final Exam**	**To be announced**		

Expected workload

On average students need to spend 2 hours of study and preparation for each 50-minute lecture/tutorial.

Attendance policy

Absence from lectures and/or tutorials shall not exceed 15%. Students who exceed the 15% limit without a medical or emergency excuse acceptable to and approved by the Dean of the relevant college/faculty shall not be allowed to take the final examination and shall receive a mark of zero for the course. If the excuse is approved by the Dean, the student shall be considered to have withdrawn from the course.

Other Education Resources

Books

1. Joseph D. Nally. Editor, Good Manufacturing Practices for Pharmaceuticals, Informa Healthcare USA, Inc, 2007.
2. Syed Imtiaz Haider, Pharmaceutical Master Validation Plan The Ultimate Guide to FDA, GMP, and GLP Compliance, A CRC Press Company, London, 2001.
3. M.H.Rubinstein, *Editor*, Pharmaceutical Product licensing: Requirements for Europe, Ellis Horwood Limited, 2005.
4. Eamonn Mullins, Statistics for the Quality Control Chemistry Laboratory, The Royal Society of Chemistry, 2003.

5. Kim Huynh-Ba, Editor, Handbook of Stability Testing in Pharmaceutical Development, Springer, 2009.
6. James Agalloco and Frederick J. Carleton, Validation of Pharmaceutical Processes, Third edition, Informa, 2008.
7. Ira R. Berry and Robert P. Martin, Editors, The Pharmaceutical Regulatory Process, Informa, 2008.

Websites

Some websites are mentioned in the textbook at the end of each chapter. Other sites will be given during the classes and may be given as assignments to the students.

Assessment of the learning outcomes

All the expected learning outcomes of the course mentioned above are directly related to each of the topics planned to be covered and shall be assessed based on quizzes, the two major exams, the final exam and the homework assignments. The targeted performance in all of the stated learning outcomes is expected to be 60-90% of the total course grade.

Description of the tools used to assess the learning outcomes

1. The quizzes will be mainly subjective questions (short-answer essay, extended-response essay, and problem solving). These quizzes will cover the material taught during one to two weeks.
2. The First major exam will cover the material taught from the beginning of the semester up to the exam date. The second major exam will cover the material taught after the first exam up to the date of the exam. The final exam will cover the course material with more emphasis on the topics taught after the second exam. The questions will be objective (multiple-choice, true-false, matching and completion) and subjective questions.
3. The homework assignments will be selected from the problems given the presentation. Students will be requested to repeat the solution of the examples given in the lectures using the Excel function. The assignments will be communicated to students through the Moodle Platform. The students will be requested to post their homework assignments on the Moodle.