The Hashemite University
Faculty of Science
Course Outline

Department: Chemistry.	
Year : 2017/2018	**Semester :** *Second Semester*

Course Information	
Course Title	**Industrial Analysis – Methods Validation**
Course Number	110103413.
Pre-requisite	110103311
Course Credits	3 (2 lectures + 3 lab. hours).
Designation	Elective
Course Time	Sun, Tue: 12-1. + Lab: Sun, Tue: 1-4
Instructor	***Dr. Ayman A. Issa.***
Office Location	Chem. 208.
Office Hours	Sun, Tue: 11-12 + during the lab session.
E-mail	**aymani@hu.edu.jo**

Course Description (Catalog):

Subjects dealing with industrial analyses like validation in pharmaceutical and food industries, documentation types and documenting industrial analyses regarding quality, quality control and quality assurance. Detailed validation studies for instruments used in analysis and full validation for instrumental methods along with stability and stress studies and the required statistical evaluation. Methods of sample dissolution and preparation. The course includes the analysis of real samples, which include pharmaceutical samples, foods and drinks, fertilizers, insecticides, water and pollutants.

Text Book and References	
Text Book	Pharmaceutical Process Validation. Edited by: Ira Berry and Robert Nash. Marcel Dekker, Inc., 1993, 2nd Edition.
References	1. **Development and Validation of Analytical Methods**, Edited by C. M. Riley and T. W. Rosansk, Elsevier Science Ltd, 1996.
	2. **Sample Preparation Techniques in Analytical Chemistry**, Edited by Somenath Mitra, John Wiley & Sons, Inc., 2003.
	3. Any library book related to validation in industrial processes, especially in the pharmaceutical industry, as well as, instrumental analysis references.

Grading Plan		
Assessment Type	**Expected Date**	**Weight**
Mid-term Exam	March 20, 2018	30%
Lab Section, Evaluation, Assignments, & Quizzes	Every Lab and Lecture	30% * 15% for lab reports and assignments. * 10% for homeworks, quizzes, and evaluation. * 5% for validation report
Final Exam	May 5 - 17, 2018	40%

Teaching and Learning Methods
Lectures using an LCD projector (data show). **Lab sessions** are designed to perform the basic principles in the material, which includes lab reports during the lab session and homework assignments. **Discussion** between the groups (task forces) at the end of each lab session. Each group will **analyze a real sample**, perform full validation for the analytical method used, and submit the required validation report.
All material and references will be available on my web page http://staff.hu.edu.jo/aymani

Course Contents (Lectures)		
Week	**Topics**	**Application Lab No.**
1 - 3	**Chapter 1: General Information of Validation**: Validation: What is validation? When it is needed? Why to validate? Who makes it? Definition of terms. Types.	1
4,5	**Chapter 2: Documentations:** Definitions, Some types of documents.	
6-8	**Chapter 3: Quality**: QA & QC. Documentation in QC & QA including SOPs.	2
9, 10	**Quality**: Different types of log books/note books and their rules	3,5,6
11, 12	**Chapter 4: Introduction to instrument validation:** Prequalification, qualification (installation/operational), process qualification, and process validation.	7
13, 14	**Chapter 5: Methods validation:** Definition of terms, Analytical methods; sources, writing, authorization and validation	8,9
14, 15	**Chapter 6: Methods validation:** Statistical quality control charts, process capability, out of specification cases.	4
16	**Chapter 7: HPLC** method development**.**	

	Course Contents (Lab sessions)	Time 1:00-4:00
Week No.	**Lab Activity**	**Date**
2	**1. General Information:** Task Force and Data Collection.	6/2/2018 (**sec 1+2**); (1:00-4:00)
3	**2. Documentations:** Standard Operating Procedures (SOPs).	13/2/2018 & 18/2/2018
4	**3. Quality:** Log Books / Notebooks.	20/2/2018 & 25/2/2018
5	**4. Quality:** Control Charts. – Lecture during lab hours –	27/2 (**sec 1+2**); (12:00-2.00)
6a	**5. Quality:** Sample log-in.	4/3/2018 & 6/3/2018
6b	**6. Quality:** Analytical Reports.	4/3/2018 & 6/3/2018
7a	**7. Instrument Validation:** Installation Qualification (IQ) and Operation Qualification (OQ).	Lecture: (12:00-2:00) 11/3/2018 (**sec 1+2**)
7b	**8. Methods Validation:** Analytical Methods.	
7c	**9. Analytical Methods validation**. Methods include spectrometric methods (atomic and uv) and chromatographic (GC & HPLC).	Lecture: (12:00-3:00) 13/3/2018 (**sec 1+2**)
Final Date for choosing the Validation Project		*13/3/2018*
8	Mid-Term Exam	*20/3/2018*
9-12	**10.** Analytical Methods validation Project.	25/3/2018 & 27/3/2018 1/4/2018 & 3/4/2018 8/4/2018 & 10/4/2018 15/4/2018 & 17/4/2018
9-13	**11.** Discussion of the validation performed by all groups, including evaluation and quizzes (oral and written).	25/3/2018 – 24/4/2018
14	*Final Date for Submitting the Validation Report*	*29/4/2018*
15,16	*Final Exams*	*5-17/5/2018*

❖ **Course Objectives:**

The course aims at learning general ideas about analytical industrial methods and how to perform complete validation for analytical methods, especially those dealing with pharmaceutical industry. The student will learn how to write different type of documents needed in the validation process, quality control, and quality assurance, as well as learning many statistical methods used in methods validation.

❖ **Specific Outcomes of Instruction (Course Learning Outcomes):**

After completing this course, the students will be able to:

	Course Learning Outcomes (CLO)	(SO*)
CLO1	Discuss general ideas about analytical industrial methods	a, e
CLO2	Write different type of documents needed in the validation process, quality control, and quality assurance	a, b, d, e
CLO3	Perform a complete instrument validation for an instrument used in the lab	a, d, e
CLO4	Perform many statistical methods used in methods validation. These methods include known basic methods and advanced methods as control charting and ANOVA.	a, c, d, e
CLO5	Perform a complete sampling and analysis for a real sample from our environment (pharmaceuticals, foods and drinks, fertilizers, insecticides, water and pollutants. Sampling steps include digestion, ashing and wet ashing. Instruments used include HPLC, GC, UV and UV-visible spectrophotometers, AAS and Flame photometer.	a, b, d, e, f
CLO6	Perform a complete validation for the applied analytical methods, especially those dealing with pharmaceutical industry	a, b, c, e
CLO7	Write a validation report for the employed analytical method in the analysis project	a, c, e
CLO8	Discuss the applications of documents and process validation in pharmaceutical industry, as well as other important industries in Jordan.	a, b, c, d, e, f

*(SO) = Student Outcomes Addressed by the Course.

❖ **Student Outcomes (SO) Addressed by the Program:**

#	Outcomes Description Chemistry Student Outcomes	Contribution
(a)	Recognize and explain the fundamentals of the main areas of chemistry: Analytical, Organic, Inorganic, and Physical.	H
(b)	Explain principles and theories related to chemical structure, reactivity, reaction mechanisms, and properties of matter.	H
(c)	Perform mathematical calculations and data analysis related to chemistry disciplines.	H
(d)	Perform experimental procedures and lab measurements, examine data, and interpret results required to carry out a chemical research.	H
(e)	Relate and value the role of chemistry in industry and daily life.	H
(f)	Handle chemical substances and follow safety procedures and regulations in lab and workplace.	H
H = High, **M** = Medium, **L** = Low		

General Notes: (Attendance Policy) students are expected to attend every class and lab session and arrive on time in compliance with HU regulations. In case you find yourself in a situation that prevents you from attending class, lab, or exam, you have to inform your instructor. If you miss more than 4 classes for Sunday or Tuesday lectures or 1 lab session, you cannot pass the course. Makeup excuses will be accepted only for very limited justified cases, such as illness and emergencies. Missing a quiz or an exam without an acceptable excuse will result in a grade of zero. Changing your section without informing your instructor is not accepted at all.

Good Luck !

Dr. Ayman Issa