The Hashemite University
Faculty of Science
Course Outline

Department: Chemistry.	
Year : 2021/2022	**Semester :** *First Semester*

Course Information	
Course Title	**Industrial Analysis – Methods Validation**
Course Number	2001031413.
Pre-requisite	2001031311 and 2001031313,
Course Credits	3 (2 in classroom, 1 distant online)
Designation	Elective
Course Time	Sun, Tue, Thu: 12-1
Instructor	***Prof. Ayman A. Issa.***
Office Location	Chem. 208.
Office Hours	Sun, Tue: 10-11; Thu:11-12
E-mail (only this email is accepted)	**aymani@hu.edu.jo**

Course Description (Catalog):

This course deals with topics related to industry-specific analyzes, such as investigative in the food and pharmaceutical industry, types of documentation and documentation methods related to industrial analyses, especially with regard to quality, quality control and quality assurance. It also includes verification studies of the devices used in the analysis and verification of various automated analysis methods, the statistical calculations required for the purposes of verification of the analytical results, and studies of stability and severity. The material also includes practical topics related to preparing the sample for analysis and a detailed study of some industrial analysis models such as analysis of minerals and alloys and their ores, analysis of processed foods, pharmaceuticals, fertilizers and pesticides, analysis of petrochemical industries, water analyzes and environmental pollution.

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	Dec. 16, 2021	25%
Evaluation and Quizzes	Every Lecture	10%
Assignments	Every Lecture	20%
Validation Report	**Before** Jan. 11, 2022	5%
Final Exam	Jan. 15 – Jan 27, 2022	40%

Teaching and Learning Methods
Lectures using an LCD projector (data show). **Distant Online sessions** are designed to perform applications to the basic principles in the material, which includes practical activities and homework assignments. **Discussion** between the groups (task forces) at the end of each online session. Each group will perform full validation for the analytical method used, and submit the required validation report.
All material and references will be available on *MS-Teams* and *Moodle*

	Course Contents (Lectures)
Week	**Topics**
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.
4, 5	**Chapter 2: Documentations:** Definitions, Some types of documents.
6-8	**Chapter 3: Quality**: QA & QC. Documentation in QC & QA including SOPs.
9, 10	**Quality**: Different types of log books/note books and their rules
11	**Chapter 4: Introduction to instrument validation:** Prequalification, qualification (installation/operational), process qualification, and process validation.
12, 13	**Chapter 5: Methods validation:** Definition of terms, Analytical methods; sources, writing, authorization and validation
14	**Chapter 6: Methods validation:** Statistical quality control charts, process capability, out of specification cases.
15	**Chapter 7: HPLC** method development**.**

Course Contents (Practical Online Sessions)		
Week No.	**Activity**	**Date**
1	**1. General Information:** Task Force and Data Collection.	17-10-2021
2-3	**2. Documentations:** Standard Operating Procedures (SOPs).	21-10-2021, 28-10-2021
4-5	**3. Quality:** Control Charts.	4-11-2021, 11-11-2021
6-7	**3. Quality:** Log Books / Notebooks.	18-11-2021, 25-11-2021
8	**5. Quality:** Sample log-in.	2-12-2021
9	**6. Quality:** Analytical Reports.	9-12-2021
10a	**7. Instrument Validation:** Operation Qualification (OQ).	12-12-2021
10b	Mid-Term Exam	*16-12-2021*
	Final Date for choosing the Validation Project	*19-12-2021*
11	**8. Methods Validation:** Analytical Methods.	23-12-2021
12	**9. Analytical Methods validation**. Methods include spectrometric methods (atomic and uv) and chromatographic (GC & HPLC).	26-12, 28-12, 30-12-2021
13-14	**10.** Analytical Methods validation Project.	30-12-2021 to 11-1-2022
12-14	**11.** Discussion of the validation performed by all groups, including evaluation and quizzes (oral and written).	2-1-2022 to 11-1-2022
13	*Final Date for Submitting the Validation Report*	*11-1-2022*
15,16	*Final Exams*	*15-1-2022 to 27-1-2022*

❖ 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
CLO2	Discuss general ideas and definitions about process validation in industry	a, e
CLO3	Write different type of documents needed in the validation process, quality control, and quality assurance: SOP, Log-books/Notebooks and other documents.	a, b, e, f
CLO4	Write different type of documents needed in quality control, and quality assurance: Sample log-in and Analytical Report	a, b, e, f
CLO5	Perform a complete instrument validation for a lab instrument	a, b, f
CLO6	Perform many statistical methods used in methods validation. These methods include known basic methods and advanced methods as Control Charting and ANOVA.	a, b, f
CLO7	Learn about 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, c, e, f
CLO8	Perform a complete validation for the applied analytical methods, especially those dealing with pharmaceutical industry	a, b, c, e, f
CLO9	Write a validation report for the employed analytical method in the analysis project	a, b, e, f
CLO10	Discuss the applications of documents and process validation in pharmaceutical industry, as well as other important industries in Jordan.	a, d, e, f

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

❖ Student Outcomes (SO) Addressed by the Program:

#	Outcomes Description Chemistry Student Outcomes	Contribution
(a)	An ability to identify, formulate, and solve broadly defined technical or scientific problems by applying knowledge of mathematics and science and/or technical topics to areas relevant to the discipline.	H
(b)	An ability to formulate or design a system, process, procedure or program to meet desired needs.	H
(c)	An ability to develop and conduct experiments or test hypotheses, analyze and interpret data and use scientific judgment to draw conclusions.	M
(d)	An ability to communicate effectively with a range of audiences.	L
(e)	An ability to understand ethical and professional responsibilities and the impact of technical and/or scientific solutions in global, economic, environmental, and societal contexts.	H
(f)	An ability to function effectively on teams that establish goals, plan tasks, meet deadlines, and analyze risk and uncertainty.	H

H = High, **M** = Medium, **L** = Low

General Notes: (Attendance Policy) students are expected to attend every class and arrive on time in compliance with HU regulations. In case you find yourself in a situation that prevents you from attending class or exam, you have to inform your instructor. If you miss more than 4 classes, 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.

Good Luck !

Prof. Ayman Issa