Detailed Course Description - Course Plan Development and Updating Procedures/ Pharmacy Department	QF02/0408-3.0E

Faculty	Pharmacy	Department	Pharmacy
Course number	201551	Course title	**الجودة الدوائية**
Number of credit hours	3	Pre-requisite/co-requisite	**الصيدلة الصناعية**

Brief course description
This course will cover regulatory aspects for pharmaceuticals, quality assurance, documentation and records (including quality control and manufacturing documentation, document design and product license application). It will introduce the student to pharmaceutical formulation and processing. Finally it will introduce the student to health and safety regulations.

	Course goals and learning outcomes
Goal 1	Recognize importance of preformulation studies in drug formulation
Learning outcomes	1.1 Demonstrate a detailed understanding of the principles of quality assurance and GMP 1.2 Design and construct manufacturing and quality control documentation. Perform pharmaceutical development and formulation exercises. 1.3 Demonstrate detailed understanding of health and safety aspects of pharmaceutical technology and quality assurance
Goal 2	1. Understand the concepts of GMP inpharmaceutical operations.
Learning outcomes	2.1 Describe the basic concepts of Good Manufacturing Practice, especially those relevant for small-scale production of radiopharmaceutical compounds for use in humans 2.2 present formal requirements from authorities on GMP for medical drugs, laws and regulations for preparation of sterile drugs 2.3 escribe microbiological quality control, aseptic production, localities, clothing.
Goal 3	Review the use and application of each operation in relation GMP
Learning outcomes	3.1 Describe quality assurance, design of quality systems, risk analysis and risk assessment. 3.2 describe Audit, monitoring, internal and external inspections describe qualification and validation 3.3 carry out production under GMP and preparation of monographs, standard operating procedure,
Goal 4	SOP, batch protocols, exercise in aseptic production and presentation and analysis of protocols
Learning outcomes	4.1 Site Master File, SMF 4.2 Protocols (production protocols, standard operating procedures, SOP) Quality control, chemical and radiochemical identity and purity 4.3 Microbiological test and quality control.
Textbook	Textbooks: John Sharp, Good Pharmaceutical Manufacturing Practice: Rationale and

	Compliance, CRC Pr I Llc, 2005 2.The Theory and Practice of Industrial Pharmacy, Edited by. LEON LACHMAN, HERBERT A. LIEBERMAN, and JOSEPH L. KANIG. Lea & Febiger, 4th Edition. 2013.
Supplementary references	1. United States Pharmacopeia, 2016. 2. British Pharmacopeia, 2016. 3. Remington's; Pharmaceutical Sciences, 22nd 2013. Website(s): http://www.alzaytoonah.edu.jo/pharmacy/resources.htl 1. Joseph D. Nally. Good Manufacturing practice for pharmaceuticals, 6th Ed. 2007. 2. Andrew A. Signore and Terry Jacobs. Good Design Practice for GMP Pharmaceutical facilities. 2nd Ed. 2008. 3. Luis Jimenez, Microbial Contamination Control In The Pharmaceutical Industry, Taylor & Francis , 2004. 4. D.G. Watson, Pharmaceutical Analysis. A Textbook for Pharmacy Students and Pharmaceutical Chemist. Churchill Livingstone, 1999.

Course timeline				
Week	**Number of hours**	**Course topics**	**Pages (textbook)**	**Notes**
01	**1 1 1**	**Introduction to quality assurance and quality control. What differentiates quality assurance from quality control? Where do good manufacturing practices fit? Where to find the guidelines. Vocabulary. Goals vs implementation.**	Chapter	
02	**1 1 1**	**Fundamentals of good manufacturing practices Drugs vs devices Validation and verification What needs to be governed Manufacturing traceability and documentation Personnel and training Facilities and equipment**	Chapter	
03	**1 1 1**	**Quality Systems Regulations Quality plans and high-level strategies Roles of different individuals Design history files (intro) Risk management Software management**	Chapter	
04	**1 1 1**	**Cleaning; sterilization and microbiological quality control What methods are available When and how to validate Bioburden and dirt Outside vs in-house sterilization**	Chapter	

		Clean rooms and clean room management		
05	**1 1 1**	**Quality assurance of pharmaceuticals : General Aspects: Introduction to quality assurance, pharmacopeia monograph,**	Chapter	
06	**1 1 1**	**Literature collection, data handling and expression of analytical results; Documentation and record keeping; Official, international and national guidelines of testing**	Chapter	
07	**1 1 1**	**Good laboratory practices Basic tenets of GLP Visit to a laboratory that conducts work under GLP guidelines**	Chapter	
08	**1 1 1**	Validation and verification activities as part of quality assurance The role of sampling in quality control Working with biostatisticians	Chapter	
09	**1 1 1**	Document control systems and standard operating procedures Configuration management Writing standard operating procedures Travelers	Chapter	
10	**1 1 1**	Case report forms and other data records Laboratory notebooks Computer Laboratory	Chapter	
11	**1 1 1**	Validation reports Complaints and defective products Recalls Software testing methods; What should a non-expert know?	Chapter	
12	**1 1 1**	parameters of pharmaceuticals; sources of quality variation; Development of quality specifications according to current needs.	Chapter	
13	**1 1 1**	Audits of industrial sites; working with FDA auditors Organizing an internal audit	Chapter	
14	**1 1 1**	Working with the division of compliance Responding to audit reports and warning letters	Chapter	
15	**1 1 1**	Management practices to assure compliance with quality procedures. Developing timelines and budgets for implementing	Chapter	

		quality systems		
16	**1** **1** **1**	Obtaining management support and involvement Project management tools	Chapter	

Theoretical course evaluation methods and weight	Participation = 10% First exam 20% Second exam 20% Final exam 50%	**Practical (clinical) course evaluation methods**	Semester students' work = 50% (Reports, research, quizzes, etc.) Final exam = 50%

Approved by head of department		**Date of approval**	

Extra information (to be updated every semester by corresponding faculty member)

Name of teacher	Dr.Abdulla El Madani	Office Number	**222**
Phone number (extension)	291	Email	Abdulla.elmadani@zug.edu.jo
Office hours			