Hashemite University
Faculty of Pharmaceutical Sciences
Department of Pharmaceutics and Pharmaceutical Technology

Semester: Second **Year: 2021-2022**

Course Information	
Course Title	Sterilization and Aseptic Manufacturing
Course Number	131701334
Credit Hours	**2**
Prerequisites	Pharmaceutical Microbiology (131701354)

Instructor		
Name		
Office		
Office Phone	-	
Office Hours	**TBA**	
E-mail		

Course Description

This course builds up on the information that the student gain in Pharmaceutical Microbiology course. It discusses the most important features the pharmacists need to know in the area of contamination and infection control as well as the manufacture of microbiologically sterile medicines and their subsequent protection against microbial contamination and spoilage.

Course Objectives

The students are expected to understand the following after the completion of this course:

- The manufacture of microbiologically sterile medicines and their subsequent protection against microbial contamination and spoilage
- Chemical biocides and their applications in medicine manufacturing as well as clean room
- Clean room concepts, classifications and air quality and Personnel requirements
- The detection of hazardous microorganisms in medicines and available assays
- The available sterilization processes and their application in medicine manufacturing
- Sterile manufacturing's of ophthalmic as well as Parenterals as well as their packaging and available testing

- Pharmacopeias specifications for aseptic manufacturing and sterile medicines

Reading List	
1. Essential Book:	1. Hugo & Russell's Pharmaceutical Microbiology, 8th Ed., 2014 2. Essential Microbiology for Pharmacy and Pharmaceutical Sciences, Geoffrey Hanlon & Norman Hodges, 2013 3. Remington: Essentials of Pharmaceutics. Edited by Linda Felton, 2013 4. Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality Control, Michael Akers, 2010
2. Websites and online documents	1. What is a Cleanroom (or Clean Room)? https://www.youtube.com/watch?v=tVAZo2uhOB0 2. Cleanroom Design, Clean Construction, Cleanroom Service https://www.youtube.com/watch?v=F1dfb9t1D8s 3. Basic Introduction to a Clean Room: https://www.youtube.com/watch?v=ggG_smKxEBI 4. Aseptic Technique Tutorial https://www.youtube.com/watch?v=mDv-IkXBKM8 5. Exclusive Clip from "Introduction to Sterile & Aseptic Production https://www.youtube.com/watch?v=_2eWyRlQbxc 6. How Sterile Solutions are produced https://www.youtube.com/watch?v=Kjc68Z8Gt78 7. Merck Millipore Sterile Liquid Center https://www.youtube.com/watch?v=-zUfy86vRj8 8. Cook Pharmica Provides Liquid and Lyophilized Vial Filling and Finishing https://www.youtube.com/watch?v=20HbxkyW_pM

Topic	Chapters	Estimated no. of Hours
Bioburden: Counting, detecting and identifying microorganisms	Chapter 15 (2) Chapter 18 (1)	2
Antiseptics, disinfectants, and preservatives Pharmacopeial Regulations (USP testing)	Chapter 16 (2)	2-3
The manufacture of medicines: Product contamination and preservation Principles of Good Manufacturing Practice and clean room Water and air quality in sterile manufacturing facilities Personnel requirements for sterile manufacturing, Laminar Hood, HVAC system	Chapter 17 (2) Chapter 18 & 19 (1) Chapter 13 (4) Chapter 23 (1) Chapter 15 (4) Chapter 16 (4)	3
The design of sterilization processes	Chapter 18 (2)	2
Sterilization methods and sterility assurance and particle and particulate matter testing	Chapter 19 (2) Chapter 21 (1) Chapter 25 (3) Chapter 27 (4) Chapter 29 (4)	3
Sterile pharmaceutical products: -Parenteral Preparations - Ophthalmic Preparations Sterile product packaging systems package integrity test	Chapter 22 (1) Chapter 26 (3) Chapter 28 (3) Chapter 12 (4)	7

methods	Chapter 4 (4) Chapter 7 (4) Chapter 30 (4)	
Aseptic Techniques Clean Room Entry & Usage protocols Biosafety Cabinets classifications	You tube videos & lecture slides	2

Assessment	Grade	Date
First Exam	25	
Second Exam	25	
Final Exam	50	

Important regulations

♦ Workload:
2hours/ week of lecture time
Average workload students should expect to do outside class is 2 hours per week. Students are asked to watch the accompanying videos on the abovementioned websites that are related to each discussed chapter (videos will also be discussed inside the lectures)

♦ Excellent attendence is expected. According to the university policy, students who miss more than 15% of the lecture hours with or without excuse will be dismissed from the course
♦ 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 his posted office hours or by appointment
♦ Switch off your mobile or keep it silent throughout the lecture
♦ Listen well to the lecture and avoid side discussions, if you have a question, ask your instructor and not your collegue
♦ If you have any information, document your reference, if you didn't, then you broke the intellectual property rights law and the law will be applied o For more informations, visit the website: http://www.plagiarism.org/
♦ Exams are scheduled to be given throughout the semester, your are expected to attend all. If not, make-up exams will be offered for valid reasons. It may be different from regular exams in content and format.
♦ Cheating, academic diconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied

Prepeared by: Prof. Saja Hamed **Last updated on 2/26/2022** **by Prof. Saja Hamed**