

	Semester Lecturing Plan (Rencana Pembelajaran Semester)	No. Doc: SLP/PCE/H700-2PELB
	PHARMACEUTICAL INDUSTRY FACILITY	Rev : 00
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Course Identity:

Course Name : Pharmaceutical Industry Facility

Primary
References:

Graham C. Cole, "Pharmaceutical Production Facility: Design and Application", 2nd ed., CRC Press

Course Code : H700-2PELB
Study Program : Bachelor of Pharmaceutical Chemical Engineering

Faculty : Life Science and Technology
Semester : 7
Credits/ECTS : 2/3

Additional
References:

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Course Status : Elective
OFSE : No
Prerequisite/s : -
Applied for Batch Year : 2020

Learning
Outcomes:

1. Knowledge:
 - a. Understanding the criticality of cross contamination
 - b. Understanding sources of contamination and failures
2. General Skill:
 - a. Capable of analyzing air change and air flow pattern
 - b. Capable of extraction information from international standard (US-FDA, ISO, etc)
3. Specific Skill:
 - a. Capable of identifying requirements for pharmaceutical industry facility
 - b. Capable of constructing conceptual design of pharmaceutical industry facility
4. Attitude:
 - a. Continuous learning of latest industry standard
 - b. Maintaining professionalism as pharmaceutical engineer and put quality and safety as priority

Lecturer : Edhita Renesteen, M.T.
Responsible : Edhita Renesteen, M.T.
Learning Method : Explanation in class, sample problem, discussion, exercise in class, homework, question-answer

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Week (minggu ke)	Planned final ability (Kemampuan Akhir yang Diharapkan)	Study Materials/Content (Bahan Kajian)	Learning Method (Metode Pembelajaran)	Media	Assessment Indicator (Indikator Penilaian)	Assessment Weight (Bobot Penilaian)	Reference
1-2	To understand the important aspect in designing pharmaceutical manufacturing facility	<ul style="list-style-type: none"> - Quality principles - Principles of GMP - Risk assessment 	Presentation, reading, discussion, case study	Slides, videos, reading materials	Understanding the Quality Principles Understanding GMP Understanding FMEA as risk assessment tool		
3	Capable of evaluating the location preferences and sizing of pharma manufacturing facilities	<ul style="list-style-type: none"> - Selection criteria - Analytical Hierarchy Process (AHP) as decision making tools - Plant sizing 	Presentation, reading, discussion, case study	Slides, videos, reading materials	Understanding important site selection criteria Understanding and capable of using simple AHP Capable of determining plant size	10%	
4-5	Capable of constructing simple pharmaceutical plant layout	<ul style="list-style-type: none"> - Contamination prevention - Principle of flow - Human and material traffic - General layouting pattern - Containment technology 	Presentation, reading, discussion, case study	Slides, videos, reading materials	Understanding source of contamination and cross contamination Capable of analysing pharma manufacturing layout Capable of developing simple manufacturing layout	10%	
6-7	Capable of evaluating, analyse, and use current industrial standard in pharmaceutical industry facility	<ul style="list-style-type: none"> - BPOM (Indonesia) standard - FDA standard - ISO/ WHO standard - Room cleanliness classification 	Presentation, reading, discussion, case study	Slides, videos, reading materials	Understanding comparison of different standard Understanding room classification (based on ISO)		
8-9	Capable of designing conceptual OSD facility	<ul style="list-style-type: none"> - Process flow diagram to layouting - Sizing and standard compliance - Material and human flow 	Presentation, reading, discussion, case study	Slides, videos, reading materials	Capable of designing simple OSD plant		
10-11	Capable of designing conceptual Liquid and Semisolid facility	<ul style="list-style-type: none"> - Process flow diagram to layouting - Sizing and standard compliance - Material and human flow 	Presentation, reading, discussion, case study	Slides, videos, reading materials	Capable of designing simple liquid/ semisolid plant		

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12-13	Capable of designing conceptual sterile production facility	- Process flow diagram to layouting - Sizing and standard compliance - Material and human flow	Presentation, reading, discussion, case study	Slides, videos, reading materials	Capable of designing simple sterile product plant		
14	Integration/ summative evaluation				Capable of designing simple integrated pharma production facility according to international standard	80%	

Prepared by:	Reviewed by:	Approved by:
Dr.-Ing. Diah I. Widiputri	Dr. Hery Sutanto, M.Si.	Dr. Dipl.-Ing. Samuel P. Kusumocahyo
(Head of Editorial Team)	(Head of Chemical Engineering Dept.)	(Dean of LST Faculty)