Course Specification of Pharmacoepidemiology & Pharmacovigilance

I. Course Identification and General Information:						
1	Course Title:	Pharmacoepidemiology & Pharmacovigilance				
2	Course Number & Code:	Ph21028				
3	Credit hours: 2hrs	C.H				Total
		Theoretical	Practical	Training	Seminar	
		2				2
4	Study level / semester at which course is offered:	Level: - Fifth years/ Second Semester				
5	Pre –requisite (if any):	Pharmaceutics I,II,III and IV, Pharmacy care, Clinical pharm, ,pharmacokinetics, advanced drug delivery systems, Pharmaceutical Marketing, Applied and Evaluation of Pharmaceutical Research, Pharmaceutical Biostatistics, Pharmacy Management				
6	Co –requisite (if any):	-				
7	Programs in which course is offered:	Bachelor of Pharmacy				
8	Language of teaching the course:	English				
9	Department in which course is offered:	Pharmaceutics and Industrial Pharmacy				
10	Location of teaching the course:	Faculty of Pharmacy- Sana`a University				
11	Prepared by:	Prof. Dr. Maged Alwan				
12	Date of approval:					

II. Course description:

الموصف	نائب العميد لشؤون الجودة	رئيس القسم	عميد الكلية	عميدة مركز التطوير وضمان الجودة	رئيس الجامعة
ا.د.ماجد علوان	ا.د. محمود البريهي	ا.د.ماجد علوان	د.خالد الشوبة	ا.م.د. هدى العماد	ا.د. القاسم محمد عباس

This course covers the fundamentals of drug safety and pharmacoepidemiology, pharmacovigilance, including regulatory requirements, adverse event reporting, signaling reports and risk management. Also provide learners with regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet authorities safety reporting standards

III. Intended learning outcomes (ILOs) of the course:

At the end of this course, the students will be able to:

1. Demonstrate the basic knowledge of pharmacoepidemiology, pharmacovigilance and the principles of regulatory framework for clinical drug safety;
2. Describe good clinical trials and pharmacovigilance practice
3. Describe the concepts of , pharmacoepidemiology, pharmacovigilance and assessment
4. Describe the different types of adverse drug reactions and the variables that affect their incidence and severity.
5. Develop standard operating procedures for pharmacovigilance activities.
6. Plan pharmacovigilance activities.
7. Develop risk-benefit assessment procedures.
8. Assess seriousness, expectedness and causality of adverse drug events..
9. Utilize the different sources of pharmaceutical information.
10. Analysis all the encountered pharmaceutical problems and plan the strategies for their solution.
11. Use a protocol for assessment of pharmacovigilance activities.
12. Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.
13. Conduct research studies and utilize the results in different pharmaceutical fields.
14. Retrieve information from a variety of sources, including libraries, databases and internet.
15. Apply information and communication technology and work independently or as a part of team in different pharmacovigilance fields.
16. Implement presentation, writing reports and interviewing skills.

IV. Intended learning outcomes (ILOs) of the course:

(A) Knowledge and Understanding:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Knowledge and Understanding.

Program Intended Learning Outcomes (Sub-PILOs) in: Knowledge and Understanding		Course Intended Learning Outcomes (CILOs) in: Knowledge and Understanding	
After completing this program, students will be able to:		**After completing this course, students will be able to:**	
A1-	Recognize the principles of physical, clinical, social, behavioral, health and pharmaceutical sciences.	**a1-**	Demonstrate the basic knowledge of pharmacoepidemiology, pharmacovigilance and the principles of regulatory framework for clinical drug safety;
A3-	Describe the general cellular, biochemical and physiological aspects of human body and recognize the pharmacokinetics, pharmacodynamics, disease pathophysiology, and pharmacogenetic of therapeutic agents to provide pharmaceutical care and facilitate management of patient's medication, rationalize drug use and overall health needs.	**a2-**	Describe good clinical trials and pharmacovigilance practice.
		a3	Describe the concepts of pharmacoepidemiology, pharmacovigilance and assessment
		a4	Describe the different types of adverse drug reactions and the variables that affect their incidence and severity

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Knowledge and Understanding to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Knowledge and Understanding		Teaching strategies/methods to be used	Methods of assessment
completing this course, students will be able to:		▪ Lectures brainstorming and discussion	▪ Attendance ▪ Written and oral exams ▪ Quiz and Small Projects
a1-	Demonstrate the basic knowledge of pharmacoepidemiology, pharmacovigilance and the principles of regulatory framework for clinical drug safety;		
a2-	Describe good clinical trials and pharmacovigilance practice.		
a3	Describe the concepts of pharmacoepidemiology, pharmacovigilance and assessment		

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a4	Describe the different types of adverse drug reactions and the variables that affect their incidence and severity		

(B) Intellectual Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Intellectual skills

Program Intended Learning Outcomes (Sub-PILOs) in Intellectual skills		**Course Intended Learning Outcomes (CILOs) of Intellectual Skills**	
After completing this program, students will be able to:		**After completing this course, students will be able to:**	
B2-	Categorize the synthetic and natural drugs according to their mechanism of action,	**b1-**	Develop standard operating procedures for pharmacovigilance activities;
	systemic effect, therapeutic uses, contraindication and toxicity.		
B5-	5. Interpret the prescriptions, patient and clinical data, Analysis all the encountered pharmaceutical problems and plan the strategies for their solution, to develop the health care.	**b2-**	Plan pharmacovigilance activities;
		b3-	Develop risk-benefit assessment procedures;
		b4	Assess seriousness, expectedness and causality of adverse drug events.
		b5	Utilize the different sources of pharmaceutical information. .
		b6	Analysis all the encountered pharmaceutical problems and plan the strategies for their solution.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Intellectual Skills to Teaching Methods and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Intellectual Skills.		**Teaching strategies/methods to be used**	**Methods of assessment**
After completing this course, students will be able to:		Lectures, discussion and brain storming	Written , report and oral exams
b1-	Develop standard operating procedures for pharmacovigilance activities;		
b2-	Plan pharmacovigilance activities;		
b3-	Develop risk-benefit assessment procedures;		

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b4	Assess seriousness, expectedness and causality of adverse drug events.		
b5	Utilize the different sources of pharmaceutical information. .		
b6	Analysis all the encountered pharmaceutical problems and plan the strategies for their solution.		

(C) Professional and Practical Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Professional and Practical Skills

Program Intended Learning Outcomes (Sub-PILOs) in Professional and Practical Skills		Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills	
After completing this program, students will be able to:		**After completing this course, students will be able to:**	
C4-	Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.	**c1-**	Use a protocol for assessment of pharmacovigilance activities
C5-	Conduct research studies and utilize the results in different pharmaceutical fields.	**c2-**	Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.
		c3-	Conduct research studies and utilize the results in different pharmaceutical fields

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Professional and Practical Skills to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		Lectures, Problem solving sessions, tutorials, discussion and brain storming	Written and oral exams
c1-	Use a protocol for assessment of pharmacovigilance activities		

c2-	Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.		
c3-	Conduct research studies and utilize the results in different pharmaceutical fields		

(D) General / Transferable Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: General and Transferable skills

Program Intended Learning Outcomes (PILOs) in General / Transferable skills		Course Intended Learning Outcomes (CILOs) in General / Transferable skills	
After completing this program, students will be able to:		**After completing this course, students will be able to:**	
D1-	Practice independent learning needed for continuous professional Development	**d1-**	Retrieve information from a variety of sources, including libraries, databases and internet.
D4-	Take responsibility for adaptation to change needs in pharmacy practice	**d2**	Apply information and communication technology and work independently or as a part of team in different pharmacovigilance
			fields.
D5-	Apply information and communication technology and working effectively in a team.	**d3**	Implement presentation, writing reports and interviewing skills.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of General and Transferable skills to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in General and Transferable Skills		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		Lectures and discussion	Reports, project, Written and oral exams
d1-	Retrieve information from a variety of sources, including libraries, databases and internet.		

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d2	Apply information and communication technology and work independently or as a part of team in different pharmacovigilance fields.		
d3	Implement presentation, writing reports and interviewing skills.		

V. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1	Introduction to Pharmacoepidemiology & Pharmacovigilance	a1,a2, b1-4,c1-3, d13	Definition, causes, spreading, , classification	**1**	**2**
2	Harmful effect of medication and the ways of prevention	a1, b4, c1-3, d1-3	Definition, causes, spreading, Thalidomide, classification	**1**	**2**
3	Pharmacoepidemiology & Pharmacovigilance	a3,b1-3 ,c1-3, d1-3	- Definition, why, aim, main objectives, specific objectives of Pharmacoepidemiology	1	2

			& Pharmacovigilance. - Spontaneous Reporting, aim, strength and weakness of Spontaneous Reporting, other reporting, - Identification of harmful effect of medication, Evaluation of reports - Types of evaluation reports, What we record in the harmful effect of medication reports, example of harmful effect of medication.		
4	Role health professional in Pharmacovigilance	a4, b4, b5,c1-3, d1-3	- Systems of submitting Pharmacovigilance reports, objective of - Spontaneous Reporting, factors considered in shortage of submitted reports. - The perticpation of the health care team and health professional on interaction and communication on harmful effect	1	2
5	Roles of patient and consumer notification about the harmful effects of medication	a3, b3, b4,b5,c1-3, d1-3	- Benefits and positivity. - Quality of patients reports. - Importance of patients and consumers for the adverse effect of medicine	1	2

6	How to create and resolve pharmaceutical center	a4,b2, b5,b6 ,c1-3, d1-3	Objective of Pharmacovigilance	1	2
			centers, Function of Pharmacovigilance centers, The main steps for stablishment of Pharmacovigilance centers, Practical application to organize the center for Pharmacovigilance quality. Staff, equipment, etc…		
7	**Mid. Exam.**	**a1-4, b1-6,c1-3**		1	2
8	Methods used in Pharmacovigilance	a2-4,b1, b2,b6,c1-3, d1-3	- Passive surveillance. - Stimulated reporting. - Active surveillance. - Comparative observational studies. - Targeted clinical investigations. - Descriptive studies.	2	4
9	Signal identification in pharmacovigilance	a2-3,b3, b4,b6,c1-3, d1-3	- Definition of Signal. - References sources on negative responses. - Test cafeteria for events that are verified. - Ways to determine the signal. - Clinical evaluation of individual events. - Strengthen the signals.	1	2
10	Evaluation of the causal relationship in the pharmacovigilance.	a1-3,b2, b4,b5,c1-3, d1-3	Introduction Evaluation of individual situation.	1	2

11	Contact in pharmacovigilance	a2,a3,b3, b4,b5,c1-3, d1-3	- Knowledge of basic skills.	1	2
12	New information - Sources of pharmacovigilance	a2,a3,b1, b2,b4,c1-3, d1-3	Update information of Pharmacoepidemiology & Pharmacovigilance	1	2
13	Pharmacovigilance prospects	a1-4, b2-6,c1-3, d1-3	- Pharmacovigilance in national pharmaceutical policy - Elements of Pharmacovigilance in national pharmaceutical policy. - Pharmacovigilance in regulation of pharmaceutical trading. - Pharmacovigilance in clinical practice. - Future prospective of Pharmacovigilance in the Arab world.	2	4
16	Final Exam.	**a1-4, b1-6,c1-3**		1	2
Number of Weeks /and Units Per Semester				**16**	**32**

VI. a- Teaching strategies of the course:

Lecture method, Group Discussion, Problem solving sessions**,** tutorials and brainstorming.

b-Assessment Methods:

Oral Exam, Quizzes, Attendance, Participation, Short answers, reports, project, and Written exam

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark

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1	Homework Assignments	**a1-4, b1-6,d1-3**	Sporadic through the semester	**10**
2	Reports	**c1-3,d1-3**		

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
1	**Participation and quizzes**	**1-15**	**10**	10%	**a1-4, b1-6,c1-3,d1-3**
2	**Assignments**	1-15	**10**	10%	**a1-4, b1-6,c1-3,d1-3**
3	**Mid-semester exam**	**7**	**20**	20%	**a1-4, b1-6,c1-3**
5	**Final Exam**	**16**	**60**	60%	**a1-4, b1-6,c1-3**
	Total		**100**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
Two contact hours per week	None

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X. Learning Resource (MLA style or APA style)S:

1- Required Textbook(s) (maximum two)	
	1. Notes on Pharmacovigilance prepared by department staff members. 2. Ansel; H.C., (2011) Pharmaceutical Dosage Forms and drug Delivery Systems'. 9th ed ,Lea Febiger; Philadelphia; London. 3. Aulton, M.E. (ed). (2013) Pharmaceutics, the design and manufacture of medicines. 4th editio Churchill Livingstone, Edinburgh. 4. Janet woodcock M:D ,2017, Drug Safety, FDA. www.fda.gov
2- Recommended Readings and Reference Materials	
	5. Loyd, V Allen J.,2013, Remington: The Science and Practice of Pharmacy 22nd edition, Pharmaceutical Press, London. 6. Modern Pharmaceutics, 3rd edn. (1999) (Eds Banker, G.S., Rhodes, C.T.) Marcel Dekker.
3- Electronic Materials and Web Sites *etc*.	
	www.pubmed.com http://www.sciencedirect.com www.fda.gov
4- Other Learning Material:	
	J. Pharm. Sci Published articles related to the discussed topics

XI. Facilities Required:

1 - Accommodation:	- Well-equipped lecture halls with data show facilities, whiteboards, net connection, etc. - Well-equipped laboratories with all required equipment and reagents.
2 - Computing resources:	- Computer laboratory with internet facilities.

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XII. Course Improvement Processes:

1- Strategies for obtaining student feedback on effectiveness of teaching

- Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester.
- Meeting with students and faculty (once per semester).

2- Other strategies for evaluation of teaching by the instructor or by the department.

- Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester.
- Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).

3- Processes for improvement of teaching.

- Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions.
- Exploring any possible defects in the course that might encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.

4- Processes for verifying standards of students' achievement

- Checking of a sample of students' work by an independent faculty member.
- Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution.
- Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments).
- Regular follow-up of laboratory logbooks to assess the practical achievement of students.

5- Procedures for periodically reviewing of course effectiveness and planning for improvement

- Student rating and feedback
- Peer rating and feedback
- Regular meeting of the Curriculum Committee of the faculty.

6- Course development plans

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	▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

XIII. Course Policies: (including plagiarism, academic honesty, attendance etc)	
The University Regulations on academic misconduct will be strictly enforced. Please refer to ----------	
1	**Class Attendance:** ▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	**Tardy:** - Roll will be called in the very beginning of each lecture and practical class. Retardation for more than three weeks without a reasonable excursion, the student involved shall not be allowed to attend the class any longer and consequently shall be considered to be absent.
3	**Exam Attendance/Punctuality:** ▪ Exam attendance is obligatory unless being excused by the department and faculty.
	▪ Absence from assignments or exams will dealt with according to the general policy of the university.
4	**Assignments & Projects:** ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	**Cheating:** ▪ Punishment of cheating will be according to the general policy of the university in this respect.
6	**Plagiarism:** ▪ Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	**Other policies:** ▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.

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Course Plan of Pharmacoepidemiology & Pharmacovigilance

I. - Information about Faculty Member Responsible for the Course:							
Name of Faculty Member	Prof. Dr. Maged Alwan	Office Hours					
Location & Telephone No.		SAT	SUN	MON	TUE	WED	THU
E-mail							

II. Course Identification and General Information:						
1-	Course Title:	Pharmacoepidemiology & Pharmacovigilance				
2-	Course Number & Code:	Ph21028				
3-	Credit hours: 2hrs	C.H				Total
		Th.	Seminar	Pr.	F. Tr.	

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		2	-	-		2
4-	**Study level/year at which this course is offered:**	5th year/Second semester				
5-	**Pre –requisite (if any):**	Pharmaceutics I,II,III and IV, Pharmacy care, Clinical pharm, ,pharmacokinetics, advanced drug delivery systems, Pharmaceutical Marketing, Applied and Evaluation of Pharmaceutical Research, Pharmaceutical Biostatistics, Pharmacy Management				
6-	**Co –requisite (if any):**					
7-	**Program (s) in which the course is offered**	Bachelor of Pharmacy				
8-	**Language of teaching the course:**	English				
9-	**System of Study:**	Semesters				
10-	**Mode of delivery:**	Regular				
11-	**Location of teaching the course:**	Faculty of Pharmacy-Sana'a University				

III. Course description:

This course covers the fundamentals of drug safety and pharmacoepidemiology, pharmacovigilance, including regulatory requirements, adverse event reporting, signaling reports and risk management. Also provide learners with regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet authorities safety reporting standards

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4. Describe the different types of adverse drug reactions and the variables that affect their incidence and severity.
5. Develop standard operating procedures for pharmacovigilance activities.
6. Plan pharmacovigilance activities.
7. Develop risk-benefit assessment procedures.
8. Assess seriousness, expectedness and causality of adverse drug events..
9. Utilize the different sources of pharmaceutical information.
10. Analysis all the encountered pharmaceutical problems and plan the strategies for their solution.
11. Use a protocol for assessment of pharmacovigilance activities.
12. Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.
13. Conduct research studies and utilize the results in different pharmaceutical fields.
14. Retrieve information from a variety of sources, including libraries, databases and internet.
15. Apply information and communication technology and work independently or as a part of team in different pharmacovigilance fields.
16. Implement presentation, writing reports and interviewing skills.

V. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours

1	Introduction to Pharmacoepidemiology & Pharmacovigilance	a1,a2, b1-4,c1-3, d13	Definition, causes, spreading, , classification	**1**	**2**
2	Harmful effect of medication and the ways of prevention	a1, b4, c1-3, d1-3	Definition, causes, spreading, Thalidomide, classification	**1**	**2**
3	Pharmacoepidemiology & Pharmacovigilance	a3,b1-3 ,c1-3, d1-3	- Definition, why, aim, main objectives, specific objectives of Pharmacoepidemiology & Pharmacovigilance. - Spontaneous Reporting, aim, strength and weakness of Spontaneous Reporting, other reporting, - Identification of harmful effect of medication, Evaluation of reports - Types of evaluation reports, What we record in the harmful effect of medication reports, example of harmful effect of medication.	1	2
4	Role health professional in Pharmacovigilance	a4, b4, b5,c1-3, d1-3	- Systems of submitting Pharmacovigilance reports, objective of - Spontaneous Reporting, factors considered in	1	2

			shortage of submitted reports. - The perticpation of the health care team and health professional on interaction and communication on harmful effect		
5	Roles of patient and consumer notification about the harmful effects of medication	a3, b3, b4,b5,c1-3, d1-3	- Benefits and positivity. - Quality of patients reports. - Importance of patients and consumers for the adverse effect of medicine	1	2
6	How to create and resolve pharmaceutical center	a4,b2, b5,b6 ,c1-3, d1-3	Objective of Pharmacovigilance centers, Function of Pharmacovigilance centers, The main steps for stablishment of Pharmacovigilance centers, Practical application to organize the center for Pharmacovigilance quality. Staff, equipment, etc…	1	2
7	**Mid. Exam.**	**a1-4, b1-6,c1-3**		1	2
8	Methods used in Pharmacovigilance	a2-4,b1, b2,b6,c1-3, d1-3	- Passive surveillance. - Stimulated reporting. - Active surveillance. - Comparative observational studies. - Targeted clinical investigations. - Descriptive studies.	2	4

9	Signal identification in pharmacovigilance	a2-3,b3, b4,b6,c1-3, d1-3	- Definition of Signal. - References sources on negative responses. - Test cafeteria for events that are verified. - Ways to determine the signal. - Clinical evaluation of individual events. - Strengthen the signals.	1	2
10	Evaluation of the causal relationship in the pharmacovigilance.	a1-3,b2, b4,b5,c1-3, d1-3	Introduction Evaluation of individual situation.	1	2
11	Contact in pharmacovigilance	a2,a3,b3, b4,b5,c1-3, d1-3	- Knowledge of basic skills.	1	2
12	New information - Sources of pharmacovigilance	a2,a3,b1, b2,b4,c1-3, d1-3	Update information of Pharmacoepidemiology & Pharmacovigilance	1	2
13	Pharmacovigilance prospects	a1-4, b2-6,c1-3, d1-3	- Pharmacovigilance in national pharmaceutical policy - Elements of Pharmacovigilance in national pharmaceutical policy. - Pharmacovigilance in regulation of pharmaceutical trading. - Pharmacovigilance in clinical practice. - Future prospective of Pharmacovigilance in the Arab world.	2	4
16	Final Exam.	**a1-4, b1-6,c1-3**		1	2

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Number of Weeks /and Units Per Semester	16	32

VI. a- Teaching strategies of the course:

Lecture method, Group Discussion, Problem solving sessions**,** tutorials and brainstorming.

b-Assessment Methods:

Oral Exam, Quizzes, Attendance, Participation, Short answers, reports, project, and Written exam

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	**a1-4, b1-6,d1-3**	Sporadic through the semester	**10**
2	Reports	**c1-3,d1-3**		

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
1	**Participation and quizzes**	**1-15**	**10**	10%	**a1-4, b1-6,c1-3,d1-3**
2	**Assignments**	1-15	**10**	10%	**a1-4, b1-6,c1-3,d1-3**
3	**Mid-semester exam**	**7**	**20**	20%	**a1-4, b1-6,c1-3**
5	**Final Exam**	**16**	**60**	60%	**a1-4, b1-6,c1-3**
	Total		**100**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
Two contact hours per week	None

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X. Learning Resource (MLA style or APA style)S:	
5- Required Textbook(s) (maximum two)	
&	7. Notes on Pharmacovigilance prepared by department staff members. 8. Ansel; H.C., (2011) Pharmaceutical Dosage Forms and drug Delivery Systems'. 9th ed ,Lea Febiger; Philadelphia; London. 9. Aulton, M.E. (ed). (2013) Pharmaceutics, the design and manufacture of medicines. 4th editio Churchill Livingstone, Edinburgh. 10. Janet woodcock M:D ,2017, Drug Safety, FDA. www.fda.gov
6- Recommended Readings and Reference Materials	
	11. Loyd, V Allen J.,2013, Remington: The Science and Practice of Pharmacy 22nd edition, Pharmaceutical Press, London. 12. Modern Pharmaceutics, 3rd edn. (1999) (Eds Banker, G.S., Rhodes, C.T.) Marcel Dekker.
7- Electronic Materials and Web Sites *etc*.	
	www.pubmed.com http://www.sciencedirect.com www.fda.gov
8- Other Learning Material:	
	J. Pharm. Sci Published articles related to the discussed topics

XI. Facilities Required:	
	- Well-equipped lecture halls with data show facilities, whiteboards,

1 - Accommodation:	net connection, etc. - Well-equipped laboratories with all required equipment and reagents.
3 - Computing resources:	- Computer laboratory with internet facilities.

XII. Course Improvement Processes:

6- Strategies for obtaining student feedback on effectiveness of teaching

- Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester.
- Meeting with students and faculty (once per semester).

7- Other strategies for evaluation of teaching by the instructor or by the department.

- Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester.
- Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).

8- Processes for improvement of teaching.

- Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions.
- Exploring any possible defects in the course that might encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.

9- Processes for verifying standards of students' achievement

- Checking of a sample of students' work by an independent faculty member.
- Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution.
- Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments).
- Regular follow-up of laboratory logbooks to assess the practical achievement of students.

10- Procedures for periodically reviewing of course effectiveness and planning for improvement

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	▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course development plans	
	▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

XIII. Course Policies: (including plagiarism, academic honesty, attendance etc)

The University Regulations on academic misconduct will be strictly enforced. Please refer to ----------

1	**Class Attendance:** ▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	**Tardy:** - Roll will be called in the very beginning of each lecture and practical class. Retardation for more than three weeks without a reasonable excursion, the student involved shall not be allowed to attend the class any longer and consequently shall be considered to be absent.
3	**Exam Attendance/Punctuality:** ▪ Exam attendance is obligatory unless being excused by the department and faculty. ▪ Absence from assignments or exams will dealt with according to the general policy of the university.
4	**Assignments & Projects:** ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	**Cheating:** ▪ Punishment of cheating will be according to the general policy of the university in this respect.

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6	**Plagiarism:** ▪ Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	**Other policies:** ▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.