



T-104
2022

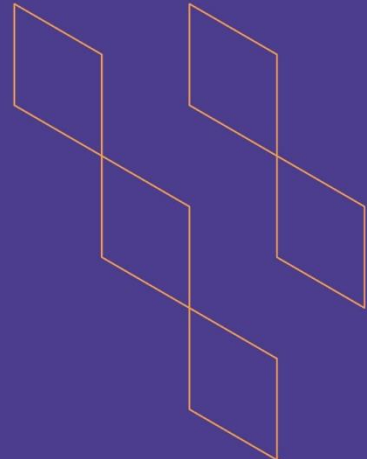
Course Specification





T-104
2022

Course Specification



Course Title: Pharmacovigilance
Course Code: 559- PHP-2
Program: Pharmaceutical Sciences
Department: Clinical Pharmacy
College: College of Pharmacy
Institution: Najran University
Version:
Last Revision Date: 14-12-2023



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A. General information about the course:

Course Identification	
1. Credit hours:	2+0
2. Course type	
a.	University <input type="checkbox"/> College <input type="checkbox"/> Department <input type="checkbox"/> Track <input type="checkbox"/> Others <input checked="" type="checkbox"/>
b.	Required <input type="checkbox"/> Elective <input checked="" type="checkbox"/>
3. Level/year at which this course is offered: 10 th Level/ 5 th Year	
4. Course general Description This course covers the fundamentals of drug safety and pharmacovigilance, including regulatory requirements, adverse event reporting, signaling reports and risk management. Also provide students with regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet authorities safety reporting standards.	
5. Pre-requirements for this course (if any): None	
6. Co- requirements for this course (if any): None	
7. Course Main Objective(s) <ul style="list-style-type: none"> • Demonstrate the basic knowledge of pharmacovigilance and the principles of regulatory framework for clinical drug safety. • Describe good clinical trials and pharmacovigilance practice. • Describe the different types of adverse drug reactions and the variables that affect their incidence and severity. 	

1. Teaching mode (mark all that apply)

No	Mode of Instruction	Contact Hours	Percentage
1.	Traditional classroom	30	100
2.	E-learning		
3.	Hybrid <ul style="list-style-type: none"> • Traditional classroom • E-learning 		
4.	Distance learning		

2. Contact Hours (based on the academic semester)

No	Activity	Contact Hours
1.	Lectures	30
2.	Laboratory/Studio	0
3.	Field	0
4.	Tutorial	0
5.	Others	0
	Total	30

B. Course Learning Outcomes (CLOs), Teaching Strategies and Assessment Methods

Code	Course Learning Outcomes	Code of CLOs aligned with program	Teaching Strategies	Assessment Methods
1.0	Knowledge and understanding			
1.1	Demonstrate the basic knowledge of pharmacovigilance and the principles of regulatory framework for clinical drug safety	K2	Lectures	Written exam
2.0	Skills			
2.1	Evaluate the pharmacovigilance reports and utilize the results in different pharmaceutical fields.	S2	Lectures	1. Written exam 2. Assignments
3.0	Values, autonomy, and responsibility			
3.1	Advocate patient rights to safe and effective medication use in relevant practice setting.	V2	Lectures	1. Written exam 2. Assignments
3.2	Review skills to work in pharmaceutical companies and pharmacy benefits management, and government public health, medicine, and other related sectors.	V4	Lectures	1. Written exam 2. Assignments

C. Course Content

No	List of Topics	Contact Hours
1.	Introduction to Pharmacovigilance	2
2.	Pharmacoepidemiology & Pharmacovigilance	2
3	Role health professional in Pharmacovigilance	2
4	Roles of patient notification about the harmful effects of medication	2
5	Methods used in Pharmacovigilance	2
6	Signal identification in pharmacovigilance	4
7	Updated sources of pharmacovigilance	2
8	Adverse Event Reporting System and Forms	4
9	Diagnosis And Managements of ADRs	4
10	Risk management systems	4
11	Examination and assessments	2
Total		30

D. Students Assessment Activities

No	Assessment Activities *	Assessment timing (in week no)	Percentage of Total Assessment Score
1.	Quiz	Regular class test	10%
2.	Midterm exam	6-7	25%
3.	Presentation	9	5%
4.	Assignments/ Clinical visit	9	5%
5.	Observation card	10	5%
6.	Final exam	12-13	50%
7	Total		100%

*Assessment Activities (i.e., Written test, oral test, oral presentation, group project, essay, etc.)



E. Learning Resources and Facilities

1. References and Learning Resources

Essential References	<ul style="list-style-type: none"> Hartzema AG, Tilson HH and Chen A. Pharmacoevidence and Therapeutic Risk Management. Harvey Whitney Press, Inc. Cincinnati 2008. Hartzema AG, Porta M, Tilson HH. Pharmacoevidence: An Introduction. Harvey Whitney Press, Inc. Cincinnati, 1998. Rothman, KJ. Epidemiology – An Introduction, 2nd Edition, Oxford University Press. ISBN: 978-0-19-975455-7 Raymond S. Greenberg, Stephen R. Medical Epidemiology, Yi Yang, Donna West-Strum. Understanding Pharmacoevidence. 2011 Brenda Waning, Michael Montagne. Pharmacoevidence: Principles and Practice. 2001
Supportive References	Students will be provided with handouts by the lecturer
Electronic Materials	http://lib.nu.edu.sa/DigitalLibrary.aspx www.rxlist.com www.drugindex.com
Other Learning Materials	

2. Required Facilities and equipment

Items	Resources
facilities (Classrooms, laboratories, exhibition rooms, simulation rooms, etc.)	A Lecture containing at least 25 seats
Technology equipment (projector, smart board, software)	<ul style="list-style-type: none"> Computer lab Internet access
Other equipment (depending on the nature of the specialty)	

F. Assessment of Course Quality

Assessment Areas/Issues	Assessor	Assessment Methods
Effectiveness of teaching	Head of departments and students	Indirect Questionnaires (indirect)
Effectiveness of students' assessment	Faculty members and students	Indirect Questionnaires (indirect)
Quality of learning resources	Student	Direct

Assessment Areas/Issues	Assessor	Assessment Methods
	peer reviewer	Indirect
The extent to which CLOs have been achieved	Students	Questionnaires (Indirect)
Other		

Assessor (Students, Faculty, Program Leaders, Peer Reviewer, Others (specify))

Assessment Methods (Direct, Indirect)

G. Specification Approval Data

COUNCIL /COMMITTEE	CLINICAL PHARMACY DEPARTMENT COUNCIL
REFERENCE NO.	
DATE	