Faculty of Pharmacy

Professional Master of Pharmacovigilance

(Credit-Hour System)

1. **Modules Description:**

The following tables represent the distribution of modules for the first and second semesters (Tables 1 and 2), and the distribution of training rounds for the third and fourth semesters (Tables 3 and 4).

Table (1): Modules of the first semester

Examination mark %					Credit hours (L+T)	Code	Title of the module
Total marks	U	T	CW	Oral			
100	50	25	15	10	3+1	PCL619	Pharmacovigilance-1
100	60	25	15	-	2+1	PCL620	Clinical Trials and Ethics
100	50	25	15	10	2+1	PCL621	Adverse Drug Reactions and Interactions-1
100	60	25	15	-	2+1	PCL622	Research Methodology and Applied Statistics
100	60	25	15	-	2+1	PCL623	Pharmacoepidemiology
					16		**Total credit hours/week**

CW: Coursework; U: unseen exam. (L+T): Lecture + Tutorial

Credit hours: 1 credit hour is equivalent to 1 lecture hour or 2 hours of practical/tutorial or 3 hours of field training per week per semester.

Table (2): Modules of the second semester

Examination mark %					Credit hours (L+T)	Code	Title of the module
Total marks	U	T	CW	Oral			
100	50	25	15	10	3+1	PCL624	Pharmacovigilance-2
100	60	25	15	-	2+1	PCL625	Evidence-Based Medicine
100	50	25	15	10	2+1	PCL626	Adverse Drug Reactions and Interactions-2
100	60	25	15	-	2+1	PCL627	Personalized Medicine
100	60	25	15	-	2+1	PCL628	Risk Assessment and Management
					16	**Total credit hours/week**	

CW: Coursework; U: unseen exam. (L+T): Lecture + Tutorial

Credit hours: 1 credit hour is equivalent to 1 lecture hour or 2 hours of practical/tutorial or 3 hours of field training per week per semester.

Table (3): Training rounds (Third semester)

Evaluation marks %				Credit hours	Code	Title of the module
Total	Case Report (1)	Case Report (2)	Oral Presentation			
100	25	25	50	7	PCL629	Market Signals* Surveillance
Evaluation after completion of the project at the end of semester 4				2	PCLp601	Research Project (Part 1)
				9	Total credit hours/week	

Credit hours: 1 credit hour is equivalent to 1 lecture hour or 2 hours of practical/tutorial or 3 hours of field training per week per semester.

*The faculty has MOUs with many drug manufacturing/pharmaceuticals companies.

Table (4): Training rounds (Fourth semester)

Evaluation marks %				Credit hours	Code	Title of the module
Total	**Case Report (1)**	**Case Report (2)**	**Oral Presentation**			
100	25	25	50	7	PCL630	Regulatory Processing*
Total	**Mini Thesis**	**Oral Presentation**	**CW**	2	PCLp601	Research Project (Part 2)
100	25	40	35			
				9	Total credit hours/week	

Credit hours: 1 credit hour is equivalent to 1 lecture hour or 2 hours of practical/tutorial or 3 hours of field training per week per semester.

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Description of modules and Training rounds

Pharmacovigilance-1	
Code: PCL619	**Credit hours: 3+1**
This module covers key concepts of pharmacovigilance including fundamentals and development of pharmacovigilance, adverse drug reaction monitoring in clinical trials, post marketing surveillance, spontaneous reporting, individual case safety reports, periodic safety update reports, causality assessment, signal management, risk management plan, and safety communication. By the end of this module, students will be familiar with the terminology and basic processes of pharmacovigilance.	
Clinical Trials and Ethics	
Code: PCL620	**Credit hours: 2+1**
This module addresses different aspects of clinical trials including design, stages as well as data interpretation and management. The ethical framework governing experimentation on human subjects such as the historical basis will be discussed. Moreover, ethical, methodological considerations, and specific regulatory requirements, including special populations in clinical trials, will be covered.	
Adverse Drug Reactions and Interactions-1	
Code: PCL621	**Credit hours: 2+1**
The module covers the general concepts and types of adverse drug reactions (ADRs), causality assessment, medication errors and the impact of pharmacogenomics on individual variation in ADRs as well as the pharmacological basis of drug interactions including drug-drug, drug-food, and drug-disease interactions. The concepts of pharmacokinetic and pharmacodynamic interactions will be addressed. The module will cover respiratory, joint & bone, gastrointestinal, endocrinological ADRs besides those related to medical devices or biologicals. Students will be able to search, compile, analyze and evaluate reports in scientific literature and databases, warnings, and risk communications about ADRs and detect potential interactions in medication lists in different clinical settings using various resources such as software and online checkers.	
Research Methodology and Applied Statistics	
Code: PCL622	**Credit hours: 2+1**
This module is designed to equip students with the fundamental tools and skills necessary for conducting rigorous research and effectively communicating scientific data. Through a combination of theoretical concepts and practical applications, students will delve into the methodologies essential for planning, executing, and presenting research in various settings. This module also covers an in-depth and focused study of advanced statistical inferential tools used in the analysis of data in different types of study designs with emphasis on sample size calculations and survival analyses. Hands-on-experience in software usage for data analysis will also be provided.	
Pharmacoepidemiology	
Code: PCL623	**Credit hours: 2+1**

This module offers the fundamental methodologies of research in pharmacoepidemiology. This involves the incorporation of content from biostatistics, epidemiology, pharmacy, as well as policy and regulatory science to study the use and effects of drugs in large populations. The module will uncover the methods, challenges, and applications of studying drug utilization patterns and safety outcomes in diverse populations. Participants will engage in hands-on exercises, case studies, and critical analysis of pharmacoepidemiologic research to critically assess and interpret their findings and contribute to the evidence-based evaluation of drug safety and effectiveness.

Pharmacovigilance-2

Code: PCL624	Credit hours: 3+1

This module covers the pharmacovigilance organizational structure, including monitoring and reporting strategies, data analysis as well as national and international regulatory aspects. During this module, students will get acquainted with top-notch methodology such as online repositories, software, monitoring, and documentation implemented in the contemporary state-of-the-art pharmacovigilance practice units. By the end of this module, students will gain hands-on- experience for the pharmacovigilance processes that are performed in practice.

Evidence-Based Medicine

Code: PCL625	Credit hours: 2+1

This module introduces students to the principles and practices of evidence-based medicine (EBM) to acquire the knowledge and develop the skills necessary for using scientific evidence in clinical decision-making. The module will cover the definition, limitations, and challenges of EBM and its importance in clinical practice. Students will learn how to search the various medical databases as well as critically appraise medical literature. The module will address the different study designs and levels of evidence, in addition to the interpretation of statistical measures in medical research. Students will also learn to communicate evidence-based findings effectively to various stakeholders, including regulatory authorities, healthcare professionals, and patients.

Adverse Drug Reactions and Interactions-2

Code: PCL626	Credit hours: 2+1

The module addresses cardiovascular, neurological, and dermatological ADRs. Students will be able to search, compile, analyze and evaluate reports in scientific literature and databases, warnings, and risk communications about ADRs and detect potential interactions in medication lists in different clinical settings regarding the studied systems using various resources including software and online checkers.

Personalized Medicine

Code: PCL627	Credit hours: 2+1

This module will shed light on the rapidly evolving field of pharmacogenomics and its impact on patient-tailored therapies. Students will learn how genetic variability influences drug responsiveness and disease progression with specific focus on the utilization of genomic data in pharmacovigilance practice. Students will conclude this module by exploring the complexities and nuances of pharmacovigilance concerning specific populations, including but not limited to pediatric, geriatric, pregnant, psychiatric, and immunocompromised populations.

Risk Assessment and Management

Code: PCL628	Credit hours: 2+1

This module addresses the fundamental principles of risk management covering different risk types, methods for risk assessment, and the various sources of risk in pharmacy practice. The module also covers the adopted approaches to minimize the likelihood of risk occurrence in clinical settings. Integrating genetic polymorphism data in risk assessment for special populations will be also explored.

Field training rounds

Market Signals Surveillance

Code: PCL629	Credit hours: 7

This training will support a multitude of monitoring and pharmacovigilance activities held at the Marketing Authorization Holder (MAH) such as:

1. Validation, prioritization, assessment, and reporting of signals.
2. Management of Qualified Person Pharmacovigilance (QPPV) Office and PV-oversight committee meetings.
3. Documenting elements and requirements of quality system, producing and following recommendations to relevant departments.
4. Processing and archiving key safety-related documents, for example the Pharmacovigilance System Master File (PSMF), Periodic Safety Update Reports (PSUR), and Risk Management Plans (RMP).
5. Developing and maintaining product risk management plans.
6. Putting the Digital Marketing department's strategies in PV-oversight such as the surveillance for product safety-related information and signal detection.
7. Communications with legal complaints and claims to assess and evaluate PV-related content.
8. Follow audits conducted by the operations audit department and their outcomes such as a corrective and preventive action (CAPA) plan and its execution.
9. Collect data from Post-authorization Safety Studies (PASS), Market research, and patient support programs.
10. Supervise voluntary revocation of marketing authorizations or the loss of authorization and generation of "sunset clause".

Regulatory Processing

Code: PCL630	Credit hours: 7

This training will support a multitude of legislative and pharmacovigilance activities held at the governmental entities such as:

1. Oversee claims, RMPs, PSMF, PSUR, and label changes.
2. Generate authorization and approvals.
3. Handle suspensions or withdrawals due to safety reasons.
4. Audit MAH abidance to local and international regulations.
5. Audit post-marketing clinical research and PV system implementation.

The students will also:

1. Submit on regular basis progress/summary reports of the different PV activities and projects held during their internship at the MAH & governmental entities to evaluate their professional and academic knowledge on how to report, summarize, and analyze PV data.
2. Present a comprehensive overview of their activities/projects during the training year.

Description of the Research Project (PCLp601):

In this program, students are required to prepare and present a project on one of the advanced topics or innovative approaches in pharmacovigilance. The project should be directly related to the training and practical experiences acquired during the program. It will be presented in the form of a mini-thesis and a presentation. The project topic will be announced at the beginning of the third semester, with the final submission due by the end of the fourth semester. Evaluation of the research project will occur at the conclusion of the fourth semester. The coursework during the third and fourth semesters will be assessed by the respective supervisors. The mini-thesis and presentations will be evaluated based on the criteria outlined in Appendix Tables X and Y, respectively.

Appendix Table (X): Rubric for evaluation of the mini thesis

Criteria	Marks	First examiner's mark	Second examiner's mark	Average mark
Introduction and literature review are recent and properly cited	5			
Methods are appropriate and clear	5			
Results are well described	5			
Discussion and conclusion are appropriate	5			
Plagiarism not more than 25%	5			
Total	25			

Appendix Table (Y) - Rubric for evaluation of the presentation

Oral Defense	Marks	First examiner's mark	Second examiner's mark	Average mark
Oral discussion	20			
Presentation (creativity, clarity, organization, ….etc)	10			
English language	10			
Total	40			