جامعة عمان العربية
AMMAN ARAB UNIVERSITY

College of Pharmacy

Department of Pharmacy

M.A Study Plan

Major Master in Pharmacovigilance & Regulatory Affairs,

Track: Comprehensive

Academic Year2024/2023

Type of Program :**Face-to-Face/Blended**

Study Plan Credit hours (33)

Teaching Type	Percentage of study plan hours/number	Actual Ratio
Complete Online E-Learning	20% - 10% Maximum	18%
Blended learning (for humanities)	60% - 40% Maximum	
Blended learning (for scientific majors)	50% - 30% Maximum	45.6%
Face-to-face learning (for humanities)	20% Minimum	
Face-to-face learning (for scientific majors)	30% Minimum	36.4%

Note: The learning types of the courses are disseminated at all academic levels in the program

Department Vision

Entrepreneurship and distinction in pharmaceutical sciences, academically and professionally, at the local, regional, and international levels.

Department Mission

Preparing pharmaceutical cadres supported by the knowledge, skills, and ethics of the profession, to meet the needs of the local, regional and global community, by local and international quality criteria.

Program Mission

Providing qualified pharmacists trained and educated at the hands of distinguished staff, conducting up-to-date research work, and building positive partnerships with community.

Educational Program Objectives

1. Equip pharmacists with knowledge, skills, and tools to build a solid body of regulatory professionals
2. Supply the pharmaceutical labour market with high-caliber professional, technical, and scientific knowledge in regulatory affairs and pharmacovigilance, keeping pace with local and international developments in the drug sector.
3. Implement global regulatory strategies and product lifecycles

Educational Program Outcomes

Students will be able to:

1. Define drug, medical device, and health care submission process requirements. (K1)
2. Apply the national healthcare legislation and regulations. (S1)
3. Articulate the critical elements in effective communications from the regulatory professional's perspective (communication and negotiating skills). (S2)
4. Evaluate the product development process. (C1)
5. Evaluate the international harmonization of regulations and clinical development and their impact on manufacturing, the submission process and drug availability. (C2)
6. Explain the roles and responsibilities of a regulatory professional in the industry. (C3)
7. Value, build and interpret safety data. (C4)
8. Interpret the pharmacovigilance data throughout the product lifecycle. (C5)
9. Appraise scientific knowledge and skills in the field of drug development and registration or re-registration and control keeping pace with the continuous changes and various

requirements in the field of regulatory affairs and drug vigilance locally and internationally. (C6)

10. Apply information technology skills in the use of software applicable to regulatory affairs submissions, document and database management systems, and research. (C7)
11. Explore and prioritize potential strategies for identified problems, design, implement, and evaluate a viable solution. (C8)
12. Correlate the post-marketing surveillance and pharmacovigilance. (C9).

Plan Contents

First: The study plan for a master's degree consists of a major in Pharmacovigilance & Regulatory Affairs of (33) credit hours disseminated as follows:

Track	Requisite Type	Credit Hours	Percent %
Thesis	Compulsory Courses	**18**	**%55**
	Elective Courses	**6**	**%18**
	Thesis	**9**	**%27**
Total			
Comprehensive	Compulsory Courses	**24**	**%73**
	Elective Courses	**9**	**%27**
Total		**33**	**%100**

Coding system approved by the University

		7	0	X	X	0	2	7
Sequence		Course Level		Knowledge domain		Major Code		College Code

Second: the Thesis Track

A. Compulsory Requisites (18) credit hours:

Teaching type			Course Number	Course Title	Credited Hours	Pre-Requisite
Online E-Learning	Blended	Face-to-Face				
		✓	70206701	Good Pharmacovigilance Operations	3	-
		✓	70206702	Regulatory and Legal Basis of Pharmacovigilance	3	-
		✓	70207702	Human Experimentation: Methodological Issues Fundamentals	3	-
✓			70207703	Global Regulatory Strategies for Pharmaceuticals	3	-
		✓	70207704	Regulatory Strategy for Product Development and Life-Cycle Management	3	-
✓			70207705	Legal Framework in Drug, Food, Health Care and Medical Device Regulation	3	-
6		12	**Total**		18	

B. Elective Requisites (6) credit hours chosen by the student from the following courses:

Teaching type			Course Number	Course Title	Credited Hours	Pre-Requisite
Online E-Learning	Blended	Face-to-Face				
	✓		70208701	Regulatory Issues in Pharmacogenomics	3	-
	✓		70208702	Project Management for Pharmaceutical Professionals	3	-

	√		70208703	Pharmaceutical Biotechnology	3	-
	√		70208704	Common Technical Documents (CTD) Submissions	3	-
	√		70208705	Special Topics in Regulatory Affairs & Pharmacovigilance	3	-
	√		70207701	Good Practice (GxP), patent guidelines, and international harmonization in Pharmaceutical Industry	3	-
	√		70208701	Benefit-Risk Management and Safety Signaling of Healthcare Products	3	-
	6		**Total**		6	

C. Thesis:

Teaching type	Credit Hours	Course Title	Course No.
Blended	3	Thesis	70209701
Blended	3	Thesis	70209702

Third: The Comprehensive Track

A. Compulsory Requisites (24) credit hours:

Teaching type			Course Number	Course Title	Credited Hours	Pre-Requisite
Online E-Learning	Blended	Face-to-Face				
		√	70206701	Good Pharmacovigilance Operations	3	-
		√	70206702	Regulatory and Legal Basis of Pharmacovigilance	3	-
	√		70206703	Benefit-Risk Management and Safety Signaling of Healthcare Products	3	-
	√		70207701	Good Practice, patent guidelines, and international harmonization in Pharmaceutical Industry	3	-
		√	70207702	Human Experimentation: Methodological Issues Fundamentals	3	-
√			70207703	Global Regulatory Strategies for Pharmaceuticals	3	-
		√	70207704	Regulatory Strategy for Product Development and Life-Cycle Management	3	-
√			70207705	Legal Framework in Drug, Food, Health Care and Medical Device Regulation	3	-
6	6	12	**Total**		24	

B. Elective Requisites (9) credit hours chosen by the student from the following courses:

Teaching type			Course Number	Course Title	Credited Hours	Pre-Requisite
Online E-Learning	Blended	Face-to-Face				
	√		70208701	Regulatory Issues in Pharmacogenomics	3	-
	√		70208702	Project Management for Pharmaceutical Professionals	3	-
	√		70208703	Pharmaceutical Biotechnology	3	-
	√		70208704	Common Technical Documents (CTD) Submissions	3	-
	√		70208705	Special Topics in Regulatory Affairs & Pharmacovigilance	3	-
	√		70208706	Pharmaceutical Analysis	3	-
			Total		9	

Course Description

70206701 Good Pharmacovigilance Operations (3 credit hours)

This course covers the process from individual case safety report (ICSR) to reporting to regulatory authorities. In addition to the requirements for a validated safety database to process ICSR in pharmacovigilance (PV). It highlights the management of PV department and the business decisions needed to manage the volume of cases received and the role of PV agreements for a PV inspection.

70206702 Regulatory and Legal Basis of Pharmacovigilance (3 credit hours)

This course covers the key regulations and the regulatory framework that influence the development and management of pharmacovigilance system. The impact of key regulatory reforms on pharmacovigilance (Brexit) and product liability issues. The impact of changing regulatory landscape on both manufacturer and regulators. It includes partnership agreements, pharmacovigilance aspects of due diligence, licensing and acquisitions, and product liability issues. It includes the Arab pharmacovigilance guidelines.

70206703 Benefit-Risk Management and Safety Signaling of Healthcare Products

(3 credit hours)

This course covers the historical overview of national and international safety requirements. It examines the processes and systems in place to support compliance with strategic documentation required for applications. In addition, it highlights the role of risk management and epidemiological methods used to identify the signals to quantify, assess, communicate adverse drug reactions. It includes in-depth understanding of the principle involved in developing, negotiating, and implementing risk management plans. Starting with background needed to develop effective benefit-risk management programs, followed by the factors contributing to the program. In addition, sources, and methods of interpretation of data as part of a risk management strategy will be included, besides the skills needed in evaluating the utility and reliability of such programs.

70207701 Good Practice, patent guidelines, and international harmonization in Pharmaceutical Industry (3 credit hours)

This course covers the regulations under the Drug, Food, and Health care products and their implication on quality of building, equipment, personnel, products, and records. It covers a wide range of issues where the 'x' represents a particular field including clinical (GCP), manufacturing (GMP), distribution (GDP). It includes the need of regulations, why were created, and are enforced worldwide, how pharmaceutical companies ensure compliance with the regulations, reasons for making quality products and the consequence for falling to comply and associated regulatory actions, and how to write the standard operating procedures (SOPs). This course will also cover international harmonization guidelines and patent guidelines.

70207702 Human Experimentation: Methodological Issues Fundamentals (3 credit hours)

This course covers the ways to lead and operate clinical trials, starting with the development of clinical plan through the completion of supporting clinical studies. Designed to familiarize the clinical research professional with predictable planning practice. Covers the basic project management methodology, drug development best practice, ethics and the soft skills needed to successfully manage a clinical trial team.

70207703 Global Regulatory Strategies for Pharmaceuticals (3 credit hours)

This course covers detailed analysis of the regulatory process for new drug approvals domestically and globally. It allows understanding the global demands from perspective of regulators, patients, healthcare providers and payers. The course provides basic understanding of the challenges and goals confronting a regulatory professional when defining a global regulatory strategy. It provides an examination of the regulatory considerations in the major regions of the world where marketing applications are pursued and compares the application requirements in these regions. It describes regulatory tools and discusses reimbursement considerations and how they may affect strategy development from both a global and regulatory perspective. Future regulatory structures in the major world markets are explored.

70207704 Regulatory Strategy for Product Development and Life-Cycle Management (3 credit hours)

This course covers development of product strategy, key factors in innovation, competition activity and customer preferences. Product cost management, market-based pricing concept, components in pricing, competitive pricing review, internal costs inputs, value proposition and strength. Learn about and ongoing product performance metrics and how to implement and monitor them.

70207705 Legal Framework in Drug, Food, Health Care and Medical Device Regulation (3 credit hours)

This course explores the essentials of drug, food, health care and medical device law and regulations and gain a comprehensive understanding of the administrative agencies that impact this industry. Learn about registration and listing procedures, elements of conducting clinical investigations, Premarket Approval Application, advertising and promotion, compliance, enforcement, and related issues.

Elective Courses

70208701 Regulatory Issues in Pharmacogenomics (3 credit hours)

This course covers the fundamentals of pharmacogenomic that describes how the genetic differences within a population affect body's response to a drug, in an attempt to personalize medicine that can be adapted to each person's own genetic makeup that led to higher therapeutic efficacy. In addition, it covers the regulations that covers the submission of these data.

70208702 Project Management for Pharmaceutical Professionals (3 credit hours)

This course focuses on domestic and international registration strategies. It covers how to achieve timelines by creating project teams, including the effective clarification of roles and responsibilities. In addition to the project planning tools, techniques and critical path management including negotiating registration strategies with the foreign agencies.

70208703 Pharmaceutical Biotechnology (3 credit hours)

This course emphasizes the regulatory and control aspects of biologics/biopharmaceuticals manufacturing as well as Quality by Design principles. It covers the major steps involved in the manufacture of biologics/biopharmaceuticals, preparation of media, fermentation, harvesting, purification, and formulation.

70208704 Common Technical Document Submissions - CTD (3 credit hours)

This course covers the evolution of global regulatory submissions from the original paper format to the current electronic common technical document and non-electronic submissions. It describes the internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries. It focuses on current regulations, tools, and specifications associated with the submissions.

70208705 Special Topics in regulatory affairs and pharmacovigilance (3 credit hours)

Covers the critical analysis of recently published non-fiction works that focus on cases within the pharmaceutical industry. This course will focus on novel approaches such as the use of AI wearable medical devices and decentralized (remote) clinical trials.

70208706 Pharmaceutical Analysis (3 credit hours)

This course covers the analytical techniques used for pharmaceutical characterization including GC, HPLC, and LC/MS. In addition to immunologic antibody-based procedures and emerging technologies