PRA CONSULTANCY

Pharmacovigilance GCC Course Certification

Starting : 3th Feb 2022

3 sessions per week over two weeks

Venue : Online

- **Discuss the history and evolution of pharmacovigilance**
- **Understand the international framework of PV**
- **Understand important regulatory aspects of PV**
- **Discuss the GCC PV system and requirements**
- **Understand how to prepare required reports for authorities or organizations**
- **Outline the role of the PV officers**
- **Learn more about SOP preparation**

Course Overview

Pharmacovigilance (PV) is a discipline which is mainly concerned with the safety of pharmaceuticals. Due to the increasing need for new drugs, pharmacovigilance is one of the fundamental parts of the product life cycle. That is why the international PV framework of regulations, policies and guidelines are essential to safeguard the public health. In the last few years, GCC countries have strengthened their pharmacovigilance laws and regulations. To market their products in the GCC, pharmaceutical companies will have to comply with both international and national PV requirements. This has created many opportunities for (new) PV professionals to advance their career and strengthen their position in the field of pharmacovigilance.

"**Pharmacovigilance GCC Certification**" course is designed for students and industry professionals, to advance their career as PV professional. This course will provide attendees with essential knowledge and practices to develop their PV expertise. The attendees will be trained by PV experts within and outside the pharmaceutical industry.

Why to Join

- To have a better understanding of the pharmacovigilance
- To gain expertise in the field of PV in the GCC region
- To continue your learning and development in PV related to the GCC region and be UpToDate with the guidelines
- To have a career growth as a QPPV or PV Officer
- To build up a solid and comprehensive foundation in pharmacovigilance
- To get certified from Dubai Pharmacy College
- To add a qualified certification to your CV
- To meet, network and share experiences with other industry colleagues

Educational Partner

Dubai Pharmacy College, the first pharmacy education institution in the Gulf region,was established in 1992 to meet the growing needs of healthcare professionals.The beginning of a long journey to excellence and continued development was set forth by the astute visionary Haj Saeed Bin Ahmed Al Lootah under the leadership of Prof.
Dr. Saeed Ahmed Khan.

The institution is committed to provide accredited pharmacy education at undergraduate and graduate level to female students based on Islamic values, advancement of pharmaceutical knowledge through research and community service in order to serve pharmacy profession, scientific community and public

Course Methodology

Our course is designed to equip participants with the real-world skills and knowledge required to be effective Pharmacovigilance professional. Our course relies on a variety of training and facilitation methodologies and techniques used whenever applicable; these methods aim to enhance participant interaction while maximizing the learning journey.

Some of these methods are:

- Interactive presentations
- Individual and team exercises
- One-to-one and group discussions
- Case studies, simulations and small projects

Who Should Attend

- Medical background professionals who need more knowledge in the field of Pharmacovigilance.
- Medical background professionals who need to be a certified PV officer.
- Pharmacists who want to pursue a career as pharmacovigilance professional
- PV officers who is looking for more knowledge in international and local pharmacovigilance
- Medical affairs professionals who require more knowledge about PV
- Fresh graduates who is looking to start their career in pharmacovigilance
- All professions related to medicine safety and quality who required more knowledge about international and local PV guidelines

Experienc : This course doesn't require previous experience in Pharmacovigilance; however, it requires a relevant experience/ knowledge and a bachelor's degree in the pharmaceutical / medical area which qualifies you to benefit from the training. We consider applicants with different background on a case-by-case basis.

Why PRA Consultancy

Upon registration to attend this course, participants will gain:

- Access to FREE webinars.
- Special extra discount of 10 % to attend any of our upcoming events (Conferences, Trainings, Courses … etc.).
- Since they have over 15 years of healthcare regulatory field, PRA Consultancy will be able to provide participants with practical and informative materials as well as a list of the industry's expert speakers.
- PRA Consultancy is well-connected with the regulatory authorities in the GCC, which enables participants to get the recent updates on the regulations and guidelines.

Type of Companies Hiring PV Professionals in GCC

- Pharmaceutical companies and manufacturers
- Biologics related sectors
- Health authorities
- Pharmaceutical consultancy companies
- Scientific offices
- Marketing authorization holder offices

Why PRA Consultancy

Upon registration to attend this course, participants will gain:

- Access to FREE webinars.
- Special extra discount of 10 % to attend any of our upcoming events (Conferences, Trainings, Courses … etc.).
- A letter from the college will be provided to each student to support them in having internship or training opportunity.
- Since they have over 15 years of healthcare regulatory field, PRA Consultancy will be able to provide participants with practical and informative materials as well as a list of the industry's expert speakers.
- PRA Consultancy is well-connected with the regulatory authorities in the GCC, which enables participants to get the recent updates on the regulations and guidelines.

Module 1: Pharmacovigilance Basics: Historical Overview, Terminology, Definitions and Classification of ADRs.

This module is a comprehensive introduction to the field of pharmacovigilance.It will present the attendees with the historical overview of the development of pharmacovigilance. Moreover, theattendees will be provided with a solid understanding of the essential terminology and concepts in pharmacovigilance.The module will also explain the classification of Adverse Drug Reactions (ADR), to provide the attendees with a complete and thorough basic understanding ofpharmacovigilance.

Module 2: The International Framework for Pharmacovigilance.

This module focuses on the international framework and global context of pharmacovigilance. Course participants will gain a firm understanding and international knowledge of the regulatory frameworks and processes that apply to pharmacovigilance, and drug safety in general. International concepts, including UMC, ICH, VigiFlow, VigiBase, WHO-DD, EudraVigilance and MedDRA will be discussed. The focus will be on drug safety monitoring, in accordance with national and international legislation and guidelines, as well as proactive strategies for risk management to improve patient safety.

Module 3: Good Vigilance Practices (GVP)

This module covers the GVP that are an essential part of pharmacovigilance.They are the international guidelines for good pharmacovigilance practices and form the basis of every aspect of pharmacovigilance. This module will guide the course participants through the GVP measures and how to use them to facilitate Pharmacovigilance, that will be in compliant to international as well as national requirements.

Module 4: Global Adverse Events Reporting System and the Individual Case Safety Reports

This module will provide a thorough understanding of the global adverse events reporting systems, including the general reporting guidelines of the Individual Case Safety Reports (ICRSs), expedited and accelerated reporting. The module will guide the course participants in the different reporting systems that are necessary for regulatory compliance in both international and national legislation regarding pharmacovigilance.

Module 5: Safety Communication & Aggregated Safety Reporting

This module will guide the attendees in the requirements that are set by the international and local authorities for safety communication, including statutory information as contained in the product information (i.e. the summary of product characteristics (SmPC), package leaflet (PL) and the labelling of the packaging) and public assessment reports. The module will also focus on aggregated safety reporting (PSUR/ PBRER/DSUR), which are an essential part of pharmacovigilance compliance.

Module 6: Signal Management System

This module will teach the basic concepts of the signal detection and signal management stages. It will discuss all essential stages, such as the collection, detection, evaluation and outcomes, including communication and actions. The module will provide a review of all key process involved and the requirements and steps that are required.

Module 7: The Pharmacovigilance System and Master File

This module will describe pharmacovigilance system and all the aspects involved in establishment, managing and reviewing the pharmacovigilance system. It will provide a clear overview of the regulatory requirements that needs to be fulfilled, in compliance with the international guidelines.

Module 8: Risk Management Measurements & Advertisements

The risk management system is developed to assess the drug safety profile of drugs. It implements all actions and precautions that need to be taken to assure minimal risk is taken, regarding the drug safety. This module will explain all important aspects of the risk management plan and discuss how the system is designed and will give you a brief on who is responsible of monitoring all the risks related to the products and to update the authorities with any change or risk report.

Module 9: PV Regulations and Reporting Systems in the GCC

The module will discuss the pharmacovigilance guidelines and reporting systems in the GCC. The course will highlight the critical requirements for adverseevent reporting and will introduce the operational requirements and regulatory processes involved in the detection, assessment and prevention of adverse drug effects. The focus will be on drug safety monitoring, in accordance with the national guidelines of the GCC countries.

Module 10: The Role of the MAH & QPPV

This module will discuss the role of the marketing authorization holder (MAH) and the qualified person for pharmacovigilance (OPPV), which play an important role in the pharmacovigilance, representing the pharmaceutical industry. This module will provide more insight into their roles and their responsibilities and their position between the industry and authorities.

REGISTRATION FORM

Pharmacovigilance GCC Course Certification

Starting : 27th May 2022

Venue : Dubai Pharmacy College, Dubai, UAE

First Name	:	----------	**Last Name**	:	----------
Education	:	----------	**Job Title:**	:	----------
Company	:	----------	**Mobile**	:	----------
Country	:	----------	**City**	:	----------
Address	:	----------	**Post Code**	:	----------
E-mail	:	----------			

Note: Please send the registration for along with a copy of the required documents below:

- CV
- National ID
- Passport

PAYMENT OPTIONS AVAILABLE

PRICES AND DISCOUNTS RATES

Dates:	EARLY REGISTRATION fee Before	fee Before	Final Price	GROUP DISCOUNTS
Discount rate:	5 Jan 2022	19 Jan 2022	3 Feb 2022	5+ Delegates 10 %
Price:	4,950	5,940	6,600	

00971 4 299 9398 info@pra-me.com www.pra-edu.com

TERMS AND CONDITIONS

All registrations are subject to our terms and conditions. By submitting your registration, you agree to be bound by the terms and conditions in full.

Payment Terms:

- The payment shall be conducted either in cash, credit/debit card or bank transfer.
- The stated amount is exclusive of Withholding Tax and other duties, taxes and transfer related charges which if applicable are payable by the client in addition to the stated amount.
- The above-mentioned investment is VAT exclusive.
- A confirmation letter and invoice will be sent upon receipt of your registration. Please note that full payment
- must be received prior to the event.
  Only those delegates whose fees have been paid in full will be admitted to the event.

Cancellation Policy

- If you are unable to attend, a replacement delegate will be welcomed in your place
- If you cancel your registration or if you fail to attend the event a 100% of your total amount will be charged.
- Due to unforeseen circumstances, PRA Consultancy reserves the right to cancel the course, change the
- programme, speaker or topics
  Selection of the trainer shall be at the discretion of PRA Consultancy. Every effort shall be made to maintain
- continuity, but if necessary, PRA Consultancy can change the trainer any time prior to commencement of the course.