PRA
CONSULTANCY

Pharmacovigilance GCC Certification

Online / Onsite

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 tip GCC region.
- To continue your learning and development in PV related to the GCC region and be up to date with the guidelines with the guidelines.
- To have a career growth as a QPPV or PV Officer.
- To build up as 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 insustry colleagues.

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
- One-to-one and group discussions

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.

The institution is committed to providing accredited pharmacy education for undergraduate and graduate-level female students, advancing pharmaceutical knowledge through research and community service in order to serve the pharmacy profession, the scientific community, and the public.

In 2005, it won the Dubai Quality Appreciation Programme award for education presented by Sheikh Mohammed bin Rashid Al Maktoum, Crown Prince of Dubai.

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 related to medicine safety and quality who required more knowledge about international and local PV guidelines

Experience: This course doesn't require previous experience in Pharmacovigilance; however, it requires a relevant experience/ knowledge and a bachelors 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.

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

Course Timings

• Sessions will start promptly at:
9:00 am and end at 2:00 pm
Saturday and Sunday of each week.

Module 1: Pharmacovigilance Basics: Introduction to PV and Classification of ADRs.

This module is a comprehensive introduction to the field of pharmacovigilance. present it will 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 of pharmacovigilance.

Module 2: PV Terminology and Abbreviations

This module will enable to learn about PV Industry terminologies and most common used abbreviations. In a most organize and helpful way to memorize these terms and use it in the future. At the end of the session participant will also able to learn to list of abbreviations and acronyms found in the field of, or connected with Pharmacovigilance

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:The Future of PV: From Compliance to Patient-Centricity.

This module explores the shift in pharmacovigilance from regulatory compliance to a patient-centered approach, highlighting the role of real-world evidence, patient engagement,.

Participants will learn how to integrate patient feedback into pharmacovigilance practices while maintaining compliance, preparing for the future of patient-focused drug safety.

Module 5: Individual Case Safety Reports Management

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 6: Medication error

This module will allow attendees to understand Relationship Between Adverse Drug Events & Medication Errors. This will enhance the knowledge of When Medication Errors Can Occur? When Documenting Medication (Prescription). Attendees will learn from Real Life Examples for Medication Error.

At the end of this module attendees will able to perform risk minimization and prevention of medication errors including identifying the Key Players in Preventing Medication Errors

Module 7: Causality Assessment

This Module provides guidance on how to assess the strength of the relationship between the drug and the event. It will cover four assessment criteria:

• The association in time and place between the drug and event • Pharmacology(features, previous knowledge of side effects) • Medical plausibility (characteristics, lab tests, pathology) • Likelihood or exclusion of other causes

Module 8: 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 9: The Pharmacovigilance System and the pharmacovigilance System 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 dear overview of the regulatory requirements that needs to be fulfilled, in compliance With the international guidelines.

Module 10: Safety Communication & Aggregated Safety Reporting

The module Will discuss the pharmacovigilance guidelines and reporting Systems in the CCC. The Course Will highlight the critical requirements for reporting and Will introduce the operational requirements and regulatory processes involved in the detection, assessment andprevention of adverse drug effects. The focus Will be on drug safety monitoring, in accordance With the national guidelines of the GCC countries.

Module 11: Handling Audits and Inspections

The inspection of an individual focus area covers the various stages of the audit process which includes Preparations for Audit and Inspection, Management of the audit execution. Participants will able to identify Key and common findings in PV audits along with Role play and real examples of PV audit situations. At the end of this module participant will be ready to handle audit and respond inspection.

Module 12: 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 13: The Role of the MAH & QPPV

The module Will discuss the pharmacovigilance guidelines and reporting Systems in the CCC. The Course Will highlight the critical requirements for reporting and Will introduce the operational requirements and regulatory processes involved in the detection, assessment andprevention of adverse drug effects. The focus Will be on drug safety monitoring, in accordance With the national guidelines of the GCC countries.

Module 14: PV Regulations and Reporting Systems

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.

Module 15 : The Future of PV: From Compliance to Patient-Centricity.

This module explores the shift in PV from regulatory compliance to a patient-centered approach, highlighting the role of real-world evidence, patient engagement,. Participants will learn how to integrate patient feedback into PV practices while maintaining compliance, preparing for the future of patient-focused drug safety.

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