بـــاوزيـــر فـــارمـــا لـلاســـتـــشـــارات

Bawazir Pharma Consulting

Comprehensive SFDA Pharmacovigilance System Explained Basic and Intermediate

Dates of The Training

26-27_December_2023
Riyadh, Saudi Arabia

2023

OVERVIEW

Understanding Pharmacovigilance System in Saudi Arabia is very important for persons working in pharmaceutical sector in the region. This course is specifically designed for persons working as Qualified Person of Pharmacovigilance (QPPV) in the regulatory affairs departments or related fields, who need knowledge of the SFDA Pharmacovigilance System and processes. This training will also enhance understanding and be beneficial to persons who work in clinical research, data management, basic research, and marketing, etc.

LEARNING OBJECTIVES

At the conclusion of this training, participants will be able to:

- Define the key principles and processes of Pharmacovigilance
- Define official regulatory policies and other issues pertinent to SFDA Pharmacovigilance System
- Describe the component of the PV System
- Understand the role and responsibilities of the QPPV
- Understand national pharmacovigilance sub-system file (national PSSF)
- Recognize SFDA oversight and processes during the post-approval phase.
- Understand ADR case assessment, PSUR and risk management.
- Interact appropriately with the SFDA regarding PV
- Understand the process of PV inspection and audits.

KEY TOPICS

- Introduction to Pharmacoepidemiology and Pharmacovigilance
- Pharmacovigilance systems and their quality systems
- Pharmacovigilance System Master File
- Qualified Person Responsible for Pharmacovigilance in Saudi Arabia
- Risk Management Systems
- Management and Reporting of Adverse Reactions to Medicinal Products
- Periodic Safety Update Reports
- Post-Authorization Safety Studies
- Signal Management
- Safety Communication
- Risk Minimization Measures
- Pharmacovigilance Inspections
- Pharmacovigilance Audits
- Basic concepts of vaccines and adverse events following immunization

WHO WILL ATTEND

Professionals working in:

- QPPV
- Pharma Regulatory Affairs
- Country Managers
- Scientific Office Managers
- Contract Research Organizations (CROs)
- Regulatory Authorities.
- Pharmacist
- Compliance

Bawazir Pharma Approach

Bawazir Pharma approach is grounded in the belief that compliance and quality should be managed as any other critical business issue. Proper quality management and a state of regulatory compliance will result in a decrease in direct costs such as rejects, and indirect costs such as adverse events and recalls.

Bawazir Pharma offers professional services to complete all aspects of regulatory affairs. The depth of our experience and knowledge acquired from our work with the Regulatory authorities ,ICH, International Standards Organization is made available to our partners. Our team can guide your organization through compilation of an original submission, perform submission maintenance and step in to support your internal staff during workload peaks.

PROGRAM OF DAY 1

08:45 – 09:00 REGESTRATION & COFFEE

09:00 – 10:30 SESSION 1

Introduction to Pharmacoepidemiology and Pharmacovigilance System

- What is pharmacoepidemiology and how has it developed?
- What is pharmacovigilance and how has it developed?
- Scope and purposes of pharmacovigilance
- Adverse drug reactions and The concept of safety
- Pharmacovigilance System and requirements
- Overview of SFDA Guideline on Good Pharmacovigilance Practices (GVP)]
- Definition of Pharmacovigilance system
- Quality, quality system and Quality cycle
- Principles for good pharmacovigilance practices
- Facilities and equipment for pharmacovigilance
- Specific quality system procedures and processes
- Operation of Pharmacovigilance in GCC

10:30 – 11:00: COFFEE BREAK

11:00 – 12:00 SESSION 2 Module I:

Pharmacovigilance System Master File

- Definition
- Structures and processes
- the applicant's pharmacovigilance system
- qualified person responsible for pharmacovigilance (QPPV)
- Change control, logbook, versions and archiving
- Pharmacovigilance system master file presentation
- national pharmacovigilance sub-system file (national PSSF)

12:00 – 12:45 SESSION 3 :

Qualified Person Responsible for Pharmacovigilance in GCC

- Responsibilities of the MAH in relation to the qualified person responsible for pharmacovigilance in GCC
- Qualifications of the qualified person responsible for pharmacovigilance in GCC
- Role of the qualified person responsible for pharmacovigilance in GCC
- National PSSF section on "QPPV"
- Training and practical experience.

12:45 -14:00 LUNCH

14:00 – 15:30 SESSION 4 Module III&IV:

Pharmacovigilance Inspections and Auditing

- Introduction
- Structures and processes
- What are the roles and responsibilities of REGULATOR?
- What are the roles and responsibilities of MAHs?
- How do you prepare for inspection?
- What are common deficiencies/findings of PV inspections?

15:30 – 16:00: COFFEE BREAK

16:00 – 17:30 SESSION 5

How to set up PVS and PV databases.

- Building the PVS
- PVS manual
- Basic SOPs
- PV databases.

17:30 END OF DAY ONE

PROGRAM OF DAY 2

09:00 – 10:30 SESSION 6 Module VI:

Management and Reporting of Adverse Reactions to Medicinal Products

- Introduction
- Structures and processes
- What are the rules governing suspected adverse reactions in GCC?
- How do you handle literature reports?
- How do you handle reporting quality; duplicates; nullify cases?

10:30 – 11:00 : COFFEE BREAK

11:00 – 12:45 SESSION 7 Module V &XVI

Risk Management Systems & Risk Minimization Measures

- Introduction
- What are the principles of Risk Management (RM)?
- What are the responsibilities of MAHs?
- How do you do RM of generic products?
- What is a pharmacovigilance plan and what does it include?
- What are risk minimization measures and their types?
- How do you evaluate risk minimization measures?

12:45 -14:00 LUNCH

14:00 – 15:45 SESSION 8 Module VII &VIII:

Periodic Safety Update Reports & Post-Authorization Safety Studies (PASS)

- Introduction
- Structures and processes
- What are the rules governing PSURs ?
- What evidence should be used in the scientific evaluation of benefit-risk balance of a medicinal product in PSUR?
- What are the rules governing PASS

15:45 – 16:15 COFFEE BREAK

16:15 – 17:30 SESSION 9 Module IX & X:

Signal Management

Introduction

- Structures and processes
- What are the roles and responsibilities of REGULATOR?
- What are the roles and responsibilities of MAHs?
- Operation within the KSA
- Roles and responsibilities of SFDA?
- Roles and responsibilities of MAHs?

17:30 END OF TRAINING

Saudi Vigilance

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REGESTRATION

REGISTRATION FEES

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
REGISTRATION FEES	SAR 6000.00
EARLY BIRDS REGISTRATION FEE PAY YOUR FEE BEFORE 24th December, 2023.	SAR 4500.00

Payment can be made by Bank Transfer

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For Registrationplease visite our website

Registration

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- SAR 1000.00
- If you do not cancel one week prior to the event start date and do not attend, you will be responsible for the full registration fee.
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EXPERT TRAINER

Prof. Saleh A Bawazir

CEO, Bawazir Pharma Consulting Center EX-Vice President for Drug Sector(SFDA)

Professor Bawazir worked as vice president for drug affairs and advisor at the SFDA. During his work, he led the drug sector development through a strategic plan and managed to establish a state of the art drug regulatory system that ensure quality, safety and efficacy of the pharmaceutical products and contributed positively to overall public health.

Under professor Bawazir supervision the SFDA built many electronic databases and regulatory framework that implement electronic Common Technical Document (eCTD) for drug submissions and established a strong regulatory framework for clinical trials and construct the Saudi Clinical Trial Registry (SCTR) Database. Under professor Bawazir leadership the drug sector at the SFDA is recognized as a leading drug authority in the region and worldwide.

Furthermore, Professor Bawazir represented the GCC for the last eight years in the Global Cooperation Group under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

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