



بأوزير فارما للاستشارات  
Bawazir Pharma Consulting



# Advance Comprehensive Pharmacovigilance

**9-10 October 2023**  
**Riyadh, Saudi Arabia**

## Course Overview:

This two-day course is designed for those who look to increase their knowledge in drug safety and will provide a comprehensive, yet practical assessment of the main regulations required to comply with SFDA regulations.

## Key topics:

1. Pharmacoepidemiological methods
2. Management of Pharmacovigilance Data
3. Spontaneous Case Processing
4. Literature searching
5. Pharmacovigilance methods
6. Signal detection
7. Causality assessment

**FOR REGISTRATION  
CLICKLINKBELOW**

[www.bawazirpharma.com](http://www.bawazirpharma.com)

Payment can be made by MADA  
or Bank Transfer

## Bank Account Details

NAME :Dr Saleh A. Bawazir Pharma  
Consulting Center

مركز د. صالح عبدالله بأوزير للاستشارات المهنية

IBAN: SA69-0500-0068-2026-1725-5000

Swift Code : INMASARI

Bank Name: Inma Bank, Saudi Arabia

## Advance Pharmacovigilance

FEES	SAUDI RIYAL
Registration fees	5000.00
Early Birds Registration Fee Pay Your Fees Before 6 <sup>th</sup> Oct, 2023.	4000.00

Contact Details : Tel : +966114100021

Mobile: +966500121286 OR +966554346650

Email: [info@bawazirpharma.com](mailto:info@bawazirpharma.com)

Website: [www.bawazirpharma.com](http://www.bawazirpharma.com)

## WHO SHOULD ATTEND?

### Professionals working as:

- QPPV
- Pharma Regulatory Affairs
- Country Managers
- Scientific Office Managers
- CROs
- Regulatory Authorities.
- Pharmacist

## DAY 1

**08:50 – 09:00 REGISTRATION and COFFEE**

### **SESSION 1: Pharmacoepidemiology and PV methods 1**

- Research Design and Methods
- Randomized controlled trials

**10:30 – 11:00 COFFEE BREAK**

### **SESSION 2: Pharmacoepidemiology and PV methods 2**

- Cohort and Case-Control Studies
- Other Observational Studies
- Case Reports and
- Case Series

**12:45 – 14:00 LUNCH BREAK**

### **SESSION 3: Management of Pharmacovigilance Data and Spontaneous Case Processing**

- Terminology
- Management of PV Data
- ICSR Processing
- Literature Searching

**15:30 – 16:00: COFFEE BREAK**

### **Session 4: Causality assessment for drugs and vaccines**

- GENERAL CONSIDERATIONS
- Objective and subjective assessments
- General understanding of causality/relationship assessment
- Factors to consider when assessing the relationship between drug and event

## DAY 2

**09:00 SESSION 5: Vaccine and herbal PV**

- Introduction
- Vaccines
- Elements to consider in vaccine PV
- Adverse Events Following Immunization (AEFI)
- AEFI surveillance in Saudi Arabia

**10:30 – 11:00 COFFEE BREAK**

### **SESSION 6 The process of Signal detection**

- Over view of Signal detection process
- Principles of signal evaluation

**12:45 – 14:00 LUNCH BREAK**

### **SESSION 7: New Trends PV Practice**

- Innovation in PV
- Medication errors relevance to PV

**15:30 – 16:00: COFFEE BREAK**

### **SESSION 8: Safety communication Module XV**

- Principles of safety communication
- Target audiences
- Content of safety communication
- Means of safety communication
- Effectiveness of safety communication
- Quality system requirements for safety communication

#### CANCELLATION POLICY

- All cancellations must be made in writing and be received at the Prof. Bawazir Pharma Consulting Center one week prior to the event start date. Cancellations are subject to an administrative fee:
- 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.
- Prof. Bawazir Pharma Consulting Center reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, Prof. Bawazir Pharma Consulting Center is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

#### TRANSFER POLICY

- You may transfer your registration to a colleague prior to the start of the event. Please notify the Prof. Bawazir Pharma Consulting Center of any such substitutions as soon as possible.
- PHOTOGRAPHY POLICY
- By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by Prof. Bawazir Pharma Consulting Center in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership

#### **Contact Details :**

Tel : +966114100021

Mobile: +966500121286 OR +966554346650

Email: info@bawazirpharma.com

Website: www.bawazirpharma.com