



# 2018

## 2nd ISoP

### Middle East

### Chapter Training









**International Society for Pharmacovigilance-Middle East Chapter**

**18 - 19 April 2018**



**Dubai - UAE**

## AT THE END OF THIS TRAINING COURSE YOU SHOULD BE ABLE TO:

-  Meet with regulators to address your questions
-  Plan and prepare for pharmacovigilance inspections
-  Know the processes for safety and risk communications
-  Learn the good documentation in pharmacovigilance from regulatory perspective
-  Understand the principles of benefit risk assessment to monitor effectiveness of risk minimization.
-  Understand the notion of signal detection & signal management

## SCIENTIFIC COMMITTEE & SPEAKERS:



### **Dr. Thamir Ashammari**

Vice President, Middle East Chapter- ISoP  
College of Pharmacy, University of Hail



### **Dr. Nasser Alqhatni**

Middle East Chapter- ISoP  
Advisor, Vice President for Drug Sector  
Saudi Food and Drug Authority (SFDA)



### **Dr. Nidaa Brwarsheeh**

Head of Jordan Rational Drug Use  
and Pharmacovigilance Department



### **Dr. Mayada Alkhakany**

President - Middle East Chapter  
Head of Pharmacovigilance - META  
Boehringer Ingelheim



**DAY 1** **18** **April** **2018**

DURATION		SPEAKER
08:00 - 09:00	Registration	
09:00 - 09:40	Pharmacovigilance differences among Arab Countries	Thamir Alshammari
09:45 - 11:00	Pharmacovigilance from regulatory Prespective	Nasser Alqahtani Nidaa Bwarsheeh
11:00 - 11:30	Coffee Break	
11:30 - 12:15	Valid vs non valid ICSR from Regulatory prespective	Nasser Alqahtani
12:15 - 12:30	Discussion and Q & A	
12:30 - 13:30	Lunch	
13:30 - 14:15	Safety related information (Reportable vs non reportable)	Mayada Alkhakany
14:15 - 15:00	Healthcare professional safety communication in arab guidelines	Thamir Alshammari
15:00 - 15:15	Coffee Break	
15:15 - 16:30	Literature review & documentation from regulatory prespective	Nasser Alqahtani Nidaa Bawarsheh
16:30 - 17:00	Q & A - Closing of First day	

**DAY 2** **19** **April** **2018**

DURATION		SPEAKER
08:00 - 09:00	Registration	
09:00 - 10:00	Signal management in Saudi Arabia	Nasser Alqahtani
10:00 - 11:00	JFDA regulations Past vs Today	Nidaa Bawarsheh
11:00 - 11:15	Coffee Break	
11:15 - 12:00	PSMF vs PSSF submission from Regulatory prespective Part 1	Nidaa Bawarsheh
12:00 - 12:45	PSMF vs PSSF submission from Regulatory prespective Part 2	Nidaa Bawarsheh
12:45 - 13:00	Discussion and Q & A	
13:00 - 14:00	Lunch	
14:00 - 14:45	Pharmacovigilance inspection: Conducting, finding and responding	Thamir Alshammari
14:45 - 15:30	Additional Risk Minimization Activities	Mayada Alkhakany
15:30 - 16:30	Q & A - Panel discussion, Group Photo & Certificates	

