PharmaKnowl Consulting

Pharmacovigilance Training

Signal Management Workshop

(Signal Detection and Data Mining)

15 and 16 March 2023

Overview

A safety signal is information on a new or known adverse event that may be caused by a medicine and requires further investigation.

Internationally, regionally and locally, all regulatory authorities worldwide and in Arab regulatory authorities (RAs) stressed in their pharmacovigilance guidelines and circulars on the importance of understanding and knowing the methods of signal management. In addition, all current pharmacovigilance guidelines in the Arab countries has a specific module for the signal management. Furthermore, some authorities are requesting a monthly reports of the signals for each pharmaceutical companies to be sent to them.

Signal management is required by both pharmaceutical companies as well as regulatory authorities and it is also part of several pharmacovigilance activities such as risk management plans, periodic safety update reports and the main one which is the individual case safety report.
Several methods are used for signal detection including the World Health Organization (WHO) – Uppsala Monitoring Center (UMC) causality assessment, Naranjo methods, Bayesian and other methods.

Workshop Objectives

- Understanding the concept of signal management.
- Get familiar with the regulatory requirements for signal management.
- Know the concept and process of signal detection and causality assessment.
- Identify the differences between these methods.
- Know how to perform the calculations that are needed for some methods.
- Understand the steps of each methods and how applying the process for each method.

Ways of the workshop

- Presentations
- Hands-On individual practice
- Group discussion

Who should attend

- Those who work in pharmacovigilance departments in pharmaceutical companies, regulatory authorities, and hospitals in all middle east countries including Saudi Arabia, GCC and other countries.
- Pharmacists or Physicians

Speaker

Dr. Thamir Alshammari

Dr. Thamir Alshammari is a consultant in pharmacovigilance and one of the experts in the middle East. He is also specialized in pharmacoepidemiology and clinical trials. He was the director of pharmacovigilance and drug safety center at the SFDA. He is the first Saudi who did his post-doctoral fellowship in the area of epidemiology and pharmacovigilance at the Food and Drug Administration (FDA) in the United States. He was selected to be one of the distinguished experts worldwide for the Xian center for drug safety and policy research in China till 2022. He is the president of the Middle East chapter at the international society of pharmacovigilance. He has done several training courses nationally and internationally in PV. Dr.AIshammari has over 110 publications in the same area.

Program

PharmaKnowl Consulting

Day 1
15 march 2023

Time	Topic
08:30 am - 09:00 am	Welcoming and introduction
09:00 am - 09:45 am	Terminology and principles of signal management
09:45 am - 10:45 am	Signal management regulation and requirements
— 10:45 am - 11:00 am	— Break
11:00 am - 12:00 pm	Causality assessment and data theories
— 12:00 pm - 01:00 pm	— Prayer and Lunch break
01:00 pm - 03:00 pm	Disproportionality measures and data mining
03:00 pm - 04:00 pm	Hands-on practice

Day 2
16 March 2023

Time	Topic
09:00 am - 10:30 am	First methods of signal management
10:30 am - 11:00 am	Hands-on practice
— 11:00 am - 11:15 am	— Break
11:15 am - 12:30 pm	Second method of signal management
12:30 pm - 01:00 pm	Hands-on practice
— 01:00 pm - 02:00 pm	— Prayer and Lunch break
02:00 pm - 03:00 pm	Third method of signal management
03:30 pm - 04:00 pm	Hands-on practice

PharmaKnowl Consulting

Registration

Registration Fees

Registration fee includes refreshment breaks and lunch.
Please note that the full amount must be received by PharmaKnowl prior to the event day.

Fees

Early Bird Registration (Until 24 Feb 2023)	Basic Registration (After 24 Feb 2023)
SAR 5,750	**SAR 6,325**
VAT Included	VAT Included

Register Here

Venue

Mövenpick Hotel and Residences
Northern Ring Branch Road,
Al Ghadeer, Riyadh

CANCELLATION POLICY

All cancellations must be sent to Support@PharmaKnowl.com, 48h prior to the event start date.

VENUE POLICY

PharmaKnowl Consulting reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, PharmaKnowl Consulting 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 anyone 48h prior to the start of the event Substitute attendees will be responsible to notify the PharmaKnowl Consulting via Support@PharmaKnowl.com.

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 PharmaKnowl Consulting in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

DATA PROTECTION

The personal information provided by you will be held on a database. Please see our privacy policy for more information.