بـاوزيـر فـارمـا لـلاسـتـشـارات
Bawazir Pharma Consulting

8 November 2022

Post Approval Activities and Compliance: Variations Guideline

Overview

This course will provide an overview and analysis of the various regulatory activities that take place post-approval: In particular, the current regulatory climate will be discussed in depth and numerous examples will be provided to illustrate effective filing of notification techniques. Common issues which have caused difficulties for pharmaceutical firms will also be discussed. The training will discuss in detail the GCC guideline for variations management and post approval commitment.

WHO SHOULD ATTEND

- **Regulatory Affair staff**
- **Scientific office staff**
- **Production manager.**
- **QA Manger**

Learning Objectives

1. Describe the role of regulatory affairs on meeting SFDA regulations
2. Understand the regulatory activities that take place post approval of their products.
3. Discuss the post approval commitment that must be met.
4. Understand the post approval commitment and how to help company comply with them.

Key Topics

Post-approval commitments

PV,
PSUR ,
RMMs

Variations management

PROF. BAWAZOR PHARMA CONSULTING CENTER

Training Program

08:45 – 09:00 REGESTRATION and COFFEE

SESSION 1: 09:00 – 10:30

Session 1: Post-approval commitments

- **Safety: PV , PSUR, safety update**
- **Stability**
- **Renewals**

10:30 – 11:00 COFFEE BREAK

SESSION 2: 11:00 – 12:30

Session 2: Variations management-1

- Site transfers
- CMC changes

12:30 – 13:30 LUNCH BREAK

Session 3: Variations management-2

- MAH transfer
- New Indication
- Other variations

FEES	SAUDI RIYAL
Registration	2000.00
Early Birds Registration **Pay Your Fees Before 21 October 2022**	**1000.00**

Bank Account Details

Payment can be made byBank Transfer

Name مركز صالح عبدالله باوزير للاستشارات المهنية

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

Swift Code : INMASARI

Bank Name: Inma Bank, SaudiArabia

CANCELLATION POLICY

- All cancellations must be made in writing and be received at the Prof. Bawazir Pharma Consulting Center office 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 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.