

Drug Safety is a primary concern throughout the lifecycle of any medicinal product. Pharmacovigilance (PV) activities is crucial for improvement of patient care, public health, and safety in relation to the Use. The training course is designed to use a blended learning approach where you will have a mixture of lectures, interactive discussions, workshops, and progress check quizzes to keep your learning experience enjoyable and memorable.

PROGRAM TRAINER

The course will be run by Dr. Samer Mohammed, PhD in Pharmacology, PV consultant and certified trainer in Pharmacovigilance with about 18 years of experience within the Pharma Industry; represented about 20 MAHs and 9 CROs in Iraq. Also, He was an auditor on GVP with GxP and lead auditor in ISO 9001 on Pharmaceutical industry. In collaboration with many PV expoert across different countries in middle east and PV representative of MAHs and local scientific Bureaus in Iraq



FEATURED TOPICS

- Background and History of PV
- Legislations and regulatory framework
- Adverse Events and ICSRs Management
- Periodic Aggregate Reports (PSUR / PBRER)
- Risk Management System
- Role of QPPV / LSR
- Quality System within PV
- PV System Files: PSMF, PSSF
- Audits and Inspections
- SDEA management with MAH

WHO SHOULD ATTEND?

Professionals working in:

- Manufacturers
- Scientific Bureau
- Marketing Authorization holders
- Students or graduates who want to pursue the career of the PV

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WHAT CAN YOU EXPECT from ATTENDING?

Upon completion of this course, you should be able to:

- UNDERSTAND THE HISTORY BEHIND THE EVOLUTION OF THE PV.
- UNDERSTAND THE LEGISLATIONS AND REGULATORY framework GLOBALLY AND in THE REGION. ● UNDERSTAND THE KEY DEFINITIONS in THE PV.
- UNDERSTAND THE JOURNEY OF ADVERSE EVENTS AS INDIVIDUAL CASES AND within THE VARIOUS TYPES of SAFETY REPORTS.
- UNDERSTAND THE CONCEPTS OF THE PERIODIC Aggregate REPORTS.
- UNDERSTAND THE RISK MANAGEMENT SYSTEM INCLUDING THE PLAN, THE MINIMIZATION MEASURES AND HOW TO MEASURE THE EFFECTIVENESS.
- UNDERSTAND THE ROLES AND RESPONSIBILITIES OF THE LOCAL SAFETY RESPONSIBLE PERSON OR QPPV AND CONDUCT DAY-TO-DAY PV ACTIVITIES.
- UNDERSTAND THE QUALITY SYSTEM WITHIN THE PV including PROCESSES, AND DOCUMENTS.
- UNDERSTAND THE DETAILS & CONTENTS OF THE VARIOUS PV FILES (PREPARATION, MAINTENANCE, UPDATES)
- UNDERSTAND THE MANAGEMENT OF AUDITS AND INSPECTIONS from THE AUDITOR AND AUDITEE PROSPECTIVE, including PREPARATIONS, AUDIT CONDUCTION AS WELL AS CORRECTIVE AND PREVENTIVE ACTIONS (CAPAS).

ABOUT VigiPulse Pharmacovigilance Solutions

Vigipulse is a third party office that responsible to provide all Pharmacovigilance solutions to local manufacturer in Iraq and local distributor to enhance their commitments with Iraqi regulatory intelligence and MAHs obligations. Vigipulse could offer wide range of services including improving Pharmacovigilance, Quality system, auditing, training, literature screening, and several other services

DISCLOSURE POLICY

VigiPulse is not promoting any product and has not received any fund from any source. It has no conflict of interest to any company or product.

All slides and contents that will be presented by the speakers are well-balanced, evidence-based, and unbiased.

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AGENDA

Training sessions	Time	Speaker
Day 1 (online)		
Welcome and career advice. Introduction to Pharmacovigilance, Terminologies, and Methods	2 Hours	Samer Mohammed
Pharmacovigilance in Pharmaceutical manufacturers	1 hour	Nada H. Al-Timeemy
Day 2 (online)		
Pharmacovigilance quality management system: Processes and quality documents management	2 hours	Reem Yaseen
How to write SOPs, tools, work instructions, trackers, templates, and forms and connections with other departments	1 hour	Samer Mohammed
Day 3 (on site)		
Practical session about the implementation of SOPs writing and management of PV documents	2 hours	Samer Mohammed
PSMF and PSSF: content, preparation, management , updating and submission according to HA regulations	1 hour	Samer Mohammed
Day 4 (online)		
ICSRs: sources, case narrative writing, medical aspects, Case processing, quality check, follow up and trackers, and archiving. Submissions to HA	2 hours	Jaafer Kurmanji
Causality assessment and Signal management	1 hour	Samer Mohammed
Day 5 (online)		
National Pharmacovigilance regulations	1 hour	
Aggregate reportings, RMP: definitions, identifications, writing, management and submission to HA	1 hour	Dina Ghassan
PSUR/ PBRER: definition, writing, management, submission to HA	1 hour	Dina Ghassan
Day 6 (online)		
Audits and Inspections: Before, During, and After. Inspection readiness, KPIs and compliance.	1 hour	Mai salama
How to conduct Literature search, global vs local journals	1 hour	Samer Mohammed
Safety data Exchange Agreement: preparing, writing, management of PV agreement between MAHs and local distributor	1 hour	Samer Mohammed
Day 7 (on site)		
Practical session about ICSR management	2 hour	Samer Mohammed
Practical session about Audit and inspection	2 hours	Samer Mohammed
Day 8 (online)		
Online Exam for attendees	1 hour	Samer Mohammed
Day 9 (onsite)		
Post-exam review and follow up. Certificates distribution, Preparing for mentoring	2 hour	Samer Mohammed

TRAINING PACKAGE OPTIONS & FEES

Essential Pharmacovigilance Training Course for LSR/QPPV in Iraq

LIGHT OPTION Budget-friendly foundation for basic PV knowledge	PRO OPTION For Attendees entering the PV field effectively	PREMIUM OPTION For companies & Scientific Bureaus
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PROPERTY / INCLUSION	LIGHT	PRO	PREMIUM
Core pharmacovigilance training content	✓	✓	✓
Recorded online training sessions	✓	✓	✓
Full access to all recorded training sessions	✓	✓	✓
VigiPulse training certificate	✓	✓	✓
Live online interactive training sessions	—	✓	✓
Onsite practical training sessions	—	✓	✓
Interactive training booklet	—	✓	✓
Interactive exercises & knowledge checks	—	✓	✓
Hard-copy certificate from American Institute for Applied Education (AIAE)	—	✓	✓
3-month mentoring program	—	—	✓
Weekly online mentoring meeting	—	—	✓
Support for implementing training in daily PV activities	—	—	✓
COURSE FEE	290,000 IQD	490,000 IQD	790,000 IQD

Enrollment & inquiries: info@Vigipulse.net | WhatsApp +9647700168800