IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Practical Requirements of the Arab Pharmacovigilance Guidelines

12-13 June 2025
+ 16-17 October 2025

Practical guidance on how to comply with the pharmacovigilance requirements in the Middle East

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

On 1 July 2015, the Common Arab Guidelines on good vigilance practices became effective. The Guidelines represented fundamental changes to pharmacovigilance practice and followed many aspects of the EU guidelines of June 2012.

This intensive two-day course will look at the various topics and their practical application from the perspective of compliance with the requirements of the Regulatory Authorities. The course will include experiences of the inspections and audits following implementation and will identify what the main focus points have been for possible inspection findings.

Benefits of attending

- **Gain** an overview of the modules and the responsibilities of the Marketing Authorisation Holder (MAH)
- **Discuss** the practical application of the modules and documentation required
- **Discover** the levels of implementing Quality Management Systems (QMS) throughout the company
- **Understand** the regulatory expectations of inspections
- **Realise** what written processes need to be in place

Who should attend?

Anyone involved in pharmacovigilance and regulatory activities in the Middle East/Arab States – including pharmacovigilance case processing, local QPPVs, medical directors, drug safety managers, QA auditing, PSUR writers, and any company managers and licence holders wanting to know what impact this will have on their business practices.

This course will also be beneficial to companies looking to expand into this geographic area.

Programme

Day 1

An introduction to the PV structure

- Overview of the modules
- The interaction of the modules
- A comparison to the EU modules

Quality management systems (QMS)

- Quality control, quality assurance and quality management
- Quality management of PV systems
- The QPPV and quality management
- Quality and training
- QA and quality management and internal audits

The Pharmacovigilance System Master File (PSMF)

- The content of the PSMF
- Licence submissions and the PSMF
- The QPPV and the PSMF
- Control/management of the PSMF

Pharmacovigilance inspections

- The purpose of the inspection
- Types of inspection
- Inspection findings
- Re-inspections

Ppharmacovigilance audits

- The purpose of company audits
- Audit scheduling and risk
- Audit outputs and findings
- Audit findings and their corrections – root cause analysis, corrective action plans, completion and re-audits

Day 2

Risk Management Plans (RMPs) and risk minimisation

- ICH E2E – pharmacovigilance planning
- The RMP purpose
- The RMP format
- Updating the RMP
- RMPs and risk evaluation & mitigation strategies (REMs)

Module VI – adverse reaction reporting (part 1)

- Definitions
- Special situations
- Triage – seriousness
- Expectedness and causality
- Expedited reporting

Module VI – adverse reaction reporting (part 2)

- Electronic ADR reporting – local and international
- Follow-up of cases
- ICH E2D – post-marketing safety
- Literature ADR reporting
- Case closure

Module VII – periodic safety update reports (PSURs)

- ICH E2F and ICH E2C (R2) – development safety update reports (DSURs) and PSURs/perdiodic benefit risk evaluation reports (PBRERs)
- Objectives of the PSURs
- Risk benefit analyses in PSURs
- The format of the PSUR
- Mapping signals and risks to the PSUR

Module IX – signals and their management and safety communication

- What is a signal?
- Signal validation
- Signal analysis and prioritisation
- Signal assessment
- Actions to be taken - safety communication

Adverse reaction reporting (part 1)

- Definitions
- Special situations
- Triage – seriousness
- Expectedness and causality
- Expedited reporting

Adverse reaction reporting (part 2)

- Electronic ADR reporting – local and international
- Follow-up of cases
- ICH E2D – post-marketing safety
- Literature ADR reporting
- Case closure

Periodic Safety Update Reports (PSURs)

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Signals and their management and safety communication

- What is a signal?
- Signal validation
- Signal analysis and prioritisation
- Signal assessment
- Actions to be taken - safety communication

Presenter

Graeme Ladds

Graeme Ladds, Director of PharSafer, has over 30 years' experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1989 as Head of Drug Safety & Medical Information, he went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. He then set up his consultancy and specialist CRO company, PharSafer Associates Ltd, where he has been involved in establishing pharmacovigilance in companies, performing audits across Europe and the USA, SOP writing, acting as QP for companies, and helping with regulatory inspections.

Course dates

12-13 June 2025	**Live online** 08:00-15:30 **UK (London)** (UTC+01) *Course code 14749*	GBP **1,499** EUR **2,099** USD **2,399**
16-17 October 2025	**Live online** 08:00-15:30 **UK (London)** (UTC+01) *Course code 15019*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 11 Sep**

How to book

Online:
ipi.academy/2263

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Very talented and experienced expert who has answers to all PV queries that you can think of. Advanced training that goes through the modules of PV in depth explaining what is between the lines of the guidelines, and illustrating by real life examples.

Shahinaz Badr
Officer
Newbridge Pharmaceuticals
Oct 22 2018

★★★★★

A wealth of experience and knowledge. Invigorating workshop and speaker

Dalal Abdulaziz
Regulatory Manager
Al Hafez Trading Est
Oct 22 2018

★★★★★

Very good, would recommend to PV colleagues in the industry

Emad Naguib
Global Safety Lead, Middle East
MSD
Oct 23 2017

★★★★☆

Excellent arrangement. Would recommend a colleague to visit website to check about interesting courses.

Layal Lutfi
Principal Consultant
Adamas Consulting Ltd
Oct 23 2017

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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