IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmacovigilance

12-14 June 2024
+ 9-11 October 2024

Understanding PhV today – a basic training course on the principles and practice of global PhV for those working in drug safety.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

This comprehensive three-day pharmacovigilance training course has been designed to provide an introductory guide for all those concerned with vigilance industry. The interactive programme will cover topics from basic pharmacovigilance principles and terminologies through to the current regulatory framework and its global impact, including drug surveillance in the EU, US and Japan. Proactive pharmacovigilance pre- and post-marketing will be addressed as will risk management, the challenges of causality assessments and effective signal detection.

Our panel of experts will offer practical guidance throughout the training course and use real-world examples and case studies to contribute to the development of your knowledge. There will also be ample opportunity to share experiences with the speakers and fellow professionals, which will further enhance your understanding of pharmacovigilance issues.

Key topics to be addressed include:

- Principles of pharmacovigilance and data resources
- Risk management, causality assessment and postauthorisation safety and efficacy studies (PASS/PAES)
- Pharmacoepidemiological studies and evolution of periodic safety update reports (PSURs), periodic benefit-risk evaluation reports (PBRERs) and development safety update reports (DSURs)
- Proactive pharmacovigilance pre- and post-marketing, risk-benefit assessment
- Pharmacovigilance regulations, clinical trial ADR reporting requirements n Drug surveillance in countries outside Europe
- Drug surveillance in countries outside Europe
- Post-marketing surveillance: observational cohort studies
- An overview of signal detection and risk management plans (RMPs)

Who should attend?

Anybody involved and interested in the daily practice of pharmacovigilance, including pharmaceutical physicians and those working in:

- Drug safety
- Adverse reaction monitoring
- R&D
- Regulatory affairs
- Registration

Programme

Day 1

Principles of pharmacovigilance and data resources

- Basic principles of monitoring drug safety
- An overview of methodology
- Data resources available for monitoring and evaluating drug safety
- Responding to drug safety signals

Risk management and risk minimisation: basic principles

- Basic principles
- Proactive strategies
- Principles of risk minimisation
- PASS and PAES

Causality assessment: clinical diagnosis of adverse events

- The principles of causality assessment with practical examples
- Medical evaluation of individual reports of adverse events
- Strategies for follow-up

The current regulatory framework and its global impact

- Overview of European regulatory framework, including 2012 EU pharmacovigilance legislation
- Implications for the global environment – the links to ICH and CIOMS recommendations
- Inspections and penalties for non-compliance
- Practical applications of definitions

European post-marketing pharmacovigilance regulations

- The role of the Pharmacovigilance Risk Assessment Committee (PRAC) and SCOPE initiative
- Quality management systems and the pharmacovigilance system master file (PSMF)
- QPPV
- Expedited reporting: solicited vs spontaneous
- Periodic reports and signal management and use of EudraVigilance
- RMPs and risk minimisation
- PASS/PAES
- Additional monitoring
- Pharmacovigilance inspections/audit
- Public hearings including first EMA hearing – September 2017
- Stakeholder involvement initiatives such as PROTECT, WEB-RADR
- New electronic reporting standards, E2B (R3), IDMP

Day 2

Proactive pharmacovigilance pre- and post-marketing

- Anticipating drug safety issues in development of small molecules and biologics
- What specific and non-specific safety monitoring should be done?
- Handling safety signals in development
- Differences between pre-marketing studies and post-marketing experience

Risk-benefit assessment

- General principles
- Quantifying risk
- Taking action to optimise risk-benefit
- Monitoring the effectiveness of risk management measures

Clinical trial ADR reporting requirements

- ICH E2A and general requirements
- Expedited reports
- EU Clinical Trials Directive, Clinical Trial Regulation and detailed guidance
- US IND requirements
- DSURs

Pharmacoepidemiological studies – basic designs, strengths, weaknesses and examples

- Real-world data is the king
- Randomisation in the real world
- Drugs and devices – it's all 'exposure'
- Tracking all patients?

Periodic reporting – PSURs and PBRERs

- Evolution of the PSUR, PBRER and DSUR
- What do we submit and when to submit it
- Practical aspects of compiling PSURs and PBRERs
- Linking DSURs, RMPs, PSURs, PBRERs and core safety information

Programme

Day 3

Drug surveillance in countries outside Europe

- US culture
- NDA and IND safety reporting
- Inspections
- Japan culture
- Post-marketing safety surveillance programmes in Japan
- Pharmacovigilance in other countries

Practicalities of signal detection

- Definitions of signals
- Regulatory guidances on signal detection by industry and regulators
- Resources for signal detection
- Quantitative vs qualitative signal detection

Examples of pharmacoepidemiological studies used in risk management

- How we weigh evidence
- Observational cohort studies
- Case control studies
- Drug registries (anti-TNFs)
- Pregnancy registries

Practicalities of risk management

- A real-world example of the development of a successful EU RMP
- Requirements of RMPs from an industry point of view
- How to write a successful RMP
- Reporting results of outcomes of activities in the RMP
- Updating a RMP

Practical pharmacovigilance workshop

- A practical case study with valuable hands-on experience
- Handling an important safety alert from regulators
- Assessment of risk
- Determining measures to respond to previously unidentified risks
- Continuing assessment and communication of risk-benefit

Presenters

Saad Shakir

Saad Shakir is a pharmacoepidemiologist and drug safety physician. He has worked in the fields of pharmacovigilance, pharmacoepidemiology and risk management for 30 years, initially at the UK Regulatory Authority, then the international pharmaceutical industry and as the Director of the Drug Safety Research Unit in Southampton. The DSRU is an academic unit associated with the University of Portsmouth. At the DSRU Saad leads a research team with an active programme for monitoring and studying the safety of medicines in populations. He has led many important drug safety studies and has worked and advised on many drug safety issues including product withdrawals, major restrictions and important safety hazards. Saad serves as a Chairman or member of Safety Advisory Boards and Data Safety Management Committees. He is an author of many book chapters and publications in scientific journals on pharmacovigilance, pharmacoepidemiology and risk management and is a member of the editorial boards for the journals Drug Safety and Pharmacoepidemiology and Drug Safety. Saad Shakir has led and co-ordinated many post graduate educational and training programmes including the MSc programme in Pharmacovigilance at the DSRU. He supervises post graduate students for higher degrees and has been involved with a number of international initiatives to promote and develop pharmacovigilance and pharmacoepidemiology. Saad Shakir is a Fellow of the Royal Colleges of Physicians in Glasgow, Edinburgh and London; a Fellow of the Faculty of Pharmaceutical Medicine; a Fellow of the International Society of Pharmacoepidemiology and a Member of the Royal College of General Practitioners in the UK.

Seema Jaitly

Dr Seema Jaitly qualified in Medicine from Charing Cross and Westminster Medical School in 1992 and worked in hospital medicine for four years. She has worked in the pharma industry for over 18 years at CROs and companies spanning clinical research, medical affairs, pharmacovigilance and the EU QPPV role. In 2010 she founded Essjay Solutions to offer pharmacovigilance services, consultancy and contracting services.
She is currently studying for an MSc in epidemiology with the London School of Hygiene and Tropical Medicine.

Shelley Gandhi

Shelley Gandhi joined NDA Group AB in 2012 and previously was with the MHRA (UK Regulatory Authority) for 19 years. She has extensive knowledge of all European regulatory processes relating to monitoring the safety of licensed medicinal products and ancillary devices and has investigated possible risks and has taken appropriate actions to minimise risk to public health through both European and National Committees.
She was Vigilance and Intelligence Research Group Unit Manager where she led a team of 30 whose primary role is to carry out risk assessment. In her final year at the MHRA, she mainly focussed on delivering the new pharmacovigilance legislation in Europe and ensuring the MHRA would be ready.
She is currently using this regulatory experience to work with industry to ensure they implement the new pharmacovigilance legislation.

John Parkinson

John Parkinson is a Data and Pharmaco-epidemiology Consultant. He previously worked as Director of the Clinical Practice Research Datalink (CPRD) at the MHRA, which developed out of the General Practice Research Database (GPRD) and NIHR Research Capability Programme. He has been instrumental in enabling record linkage of NHS data and of its wide use in the many aspects of pharmacoepidemiology as well as providing input to the pharmaceutical industry on studies and types of studies that companies may find helpful in their quest to make available effective and safe medicines

Course dates

12-14 June 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 13721*	GBP **1,349** ~~1,649~~ EUR **1,939** ~~2,359~~ USD **2,201** ~~2,669~~ **Until 08 May**
9-11 October 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 13955*	GBP **1,349** ~~1,649~~ EUR **1,939** ~~2,359~~ USD **2,201** ~~2,669~~ **Until 04 Sep**

How to book

Online:
ipi.academy/934

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

Email:
info@ipi.academy

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

★★★★★

All of the speakers were absolutely great, the talks were very interesting, informative and on a high level.

Yulia Buberman
PVG
Kamada LTD
Jan 31 2024

★★★★★

Excellent speakers and very experienced.

Joanna Jakubowicz
Deputy QPPV
Ovelle
Jan 31 2024

★★★★☆

I was hoping to gain better knowledge and better understanding of how PV works, and by attending this course I believe I have achieve that.

Christian Boateng
PV Scientist
Norgine Ltd
Dec 14 2022

★★★★☆

Content: very good. Presentation: Good Speakers: very good

Beatriz Blanco-Rodriguez
Global Regulatory Affairs & Pharmacovigilance
Life Molecular Imaging
Dec 14 2022

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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy