Book Before 12 October 2018 and SAVE £300/€420

MANAGEMENT forum

# Pharmacovigilance

## Understanding PhV today - a training course for those working on drug safety monitoring in the EU, USA and Japan

**3-5 December 2018 • 24-26 June 2019 London**

### Key topics to be addressed include:

- Principles of pharmacovigilance and data resources
- Risk management, causality assessment: and PASS /PAES studies
- Pharmacoepidemiological studies and evolution of PSURs, PBRERs and DSURs
- Pro-active pharmacovigilance pre- and post marketing, risk/benefit assessment
- Pharmacovigilance regulations, clinical trial ADR reporting requirements
- Drug surveillance in countries outside Europe
- Post-marketing surveillance: observational cohort studies
- An overview of signal detection and risk management plans

**With a panel of expert speakers**

**'A greatly organised and informative course given by driven and well informed speakers'**

Willem van Lierop, ApotheekZorg

**Includes: Interactive and practical sessions**

# Pharmacovigilance

**3-5 December 2018 • 24-26 June 2019, London**

## Why you should attend

This course aims to provide basic training for those concerned with pharmacovigilance. New entrants as well as experienced operators in drug safety monitoring will benefit from the mixture of scientific knowledge and practical guidance. In addition, detailed information will be provided on regulatory developments in pharmacovigilance in Europe, the USA, and Japan.

## Who should attend

All those involved and interested in the daily practice of pharmacovigilance, including those in:

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

## Expert faculty

**Dr Glyn Belcher**
Consultant, PV Consultancy Ltd

**Dr Ian Douglas**
Lecturer in Pharmacoepidemiology at London School of Hygiene & Tropical Medicine

**Shelley Gandhi**
Director, Pharmacovigilance & Drug Safety, NDA Regulatory Science Ltd

**Carol Markwell**
Director, Drug Safety Solutions Ltd, UK

**Dr John Parkinson**
Consultant Expert in Data and Pharmacoepidemiology

**Dr Bill Richardson**
Medical Advisor at NDA

**Professor Saad Shakir**
Director, Drug Safety Research Unit

**Dr John Talbot**
Senior Lecturer at University of Hertfordshire

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**Management Forum in-house training**

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## Day one

09.30 ▶ **Introduction and objectives**

▶ **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

10.30 ▶ **Refreshments**

10.45 ▶ **Risk management and risk minimisation: basic principles**
- Basic principles
- Proactive strategies
- Principles of risk minimisation
- PASS and PAES studies

11.30 ▶ **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

12.30 ▶ **Discussion *followed by Lunch***

14.00 ▶ **The current regulatory framework and its global impact**
- Overview of European regulatory framework, including 2012 EU pharmacovigilance legislation
- Implications for global environment - the links to ICH and CIOMs recommendations
- Inspections and penalties for non-compliance
- Practical applications of definitions

15.30 ▶ **Refreshments**

15.45 ▶ **European post-marketing pharmacovigilance regulations**

Overview of requirements which will include:
- The role of pharmacovigilance risk assessment committee and SCOPE initiative
- Quality management systems and the Pharmacovigilance System Master File (PSMF)
- QPPV
- Expedited reporting solicited v spontaneous
- Periodic reports and signal management and use of EudraVigilance
- Risk management plans and risk minimisation
- Post Authorisation Safety and Efficacy studies (PASS/PAES)
- Additional monitoring
- Pharmacovigilance Inspections/audit
- Public hearings including 1st EMA hearing September 2017
- Stakeholder involvement initiatives such as PROTECT, WEB-RADR
- New electronic reporting standards, E2B (R3), IDMP

17.15 ▶ **End of day one**

# Programme

## Day two

09.00 ▶ **Pro-active 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

10.00 ▶ **Discussion**

10.10 ▶ **Risk/benefit assessment**
- General principles
- Quantifying risk
- Taking action to optimise benefit/risk monitoring the effectiveness of risk management measures

11.10 ▶ **Discussion**

11.15 ▶ **Refreshments**

11.30 ▶ **Clinical trial ADR reporting requirements**
- ICH E2A and general requirements
- Expedited reports
- EU Clinical Trials Directive and detailed guidance (CT-3)
- US IND requirements
- Development Safety Update Reports (DSURs)

12.30 ▶ **Discussion *followed by***

13.00 ▶ **Lunch**

14.00 ▶ **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?

15.30 ▶ **Refreshments**

15.45 ▶ **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

16.45 ▶ **Discussion**

17.00 ▶ **End of day two**

## Day three

09.00 ▶ **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

10.15 ▶ **Practicalities of signal detection**
- Definitions of signals
- Regulatory guidances on signal detection by industry and regulators
- Resources for signal detection
- Quantitative *v* qualitative signal detection

11.00 ▶ **Refreshments**

11.15 ▶ **Examples of pharmacoepidemiological studies used in risk management**
- How we weigh evidence
- Observational cohort studies
- Case control studies
- Drug registries (anti-TNFs)
- Pregnancy registries

12.15 ▶ **Practicalities of risk management**

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

13.00 ▶ **Lunch**

14.15 ▶ **Practical pharmacovigilance workshop**

This session will comprise of a practical case study with valuable hands-on experience covering:
- 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

16.00 ▶ **End of course**

**A certificate of attendance for professional development will be available to each participant who completes the seminar**



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# Pharmacovigilance

**To book online go to: management-forum.co.uk/934** w

## Dates and venue

| | |
|---|---|
| 3-5 December 2018 | **Ref: 10152** |
| 24-26 June 2019 | **Ref: 10442** |

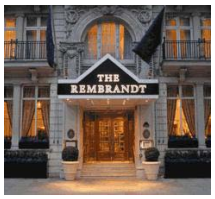
The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

**Programme schedule**

Registration and refreshments 09.00

| | |
|---|---|
| Day one | 09.30 - 17.15 |
| Day two | 09.00 - 17.00 |
| Day three | 09.00 - 16.00 |

## Accommodation

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For information on alternative accommodation please visit our website:
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## Fees and payment

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2. Online through our secure website when registering

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**FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.**

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