Book Before 23 October 2017 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

4-6 December 2017 • 19-21 June 2018 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

Includes: Interactive and practical exercises

Pharmacovigilance

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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
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

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 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**
- Prescription event monitoring
- Prospective 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**

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Dates and venue

4-6 December 2017 **Ref: 9988**
19-21 June 2018 **Ref: 10151**

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

We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact **reservations_rembrandt@sarova.co.uk** and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

For information on alternative accommodation please visit our website:
management-forum.co.uk/accommodation

Three ways to book

management-forum.co.uk

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info@management-forum.co.uk

Fees and payment

EARLY BOOKING DISCOUNT **Book BEFORE 23 October 2017**
£1549.00 + VAT = £1858.80 • €2169.00 + VAT = €2602.80

FULL PRICE **Book AFTER 23 October 2017**
£1849.00 + VAT = £2218.80 • €2589.00 + VAT = €3106.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£1571.65 + VAT = £1885.98 • €2200.65 + VAT = €2640.78

Payment options

1. Invoice which can be paid by bank transfer or credit / debit card
2. Online through our secure website when registering

In-house training

This course is also available in-house and can be tailored to your specific needs. Our experts come to you, saving you time and money. For more information contact **Customer Services** on **+44 (0)20 7749 4730** or email: **inhouse@management-forum.co.uk**

The small print

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.

HOW TO REGISTER AND PAY: A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit/debit card, by bank transfer (for bank account details please see payment details section on our website). VAT no GB 341232109. Any questions please contact Customer Services on +44 (0)20 7749 4730. **ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.**

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

Delegate	Up to 28 days before course	27 to 14 days before course	13 to 0 days before course
Cancellation	10% admin fee	100% admin fee	100% admin fee
Transfers	Free	10% admin fee	100% admin fee
Substitution	Free	Free	Free

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses. All cancellations must be received in written form.

For event cancellation policy and T&Cs see our website