Book before 15 February 2019 and SAVE £300/€420

Advanced Pharmacovigilance

To book online go to: **management-forum.co.uk/1475** W

Dates and venue

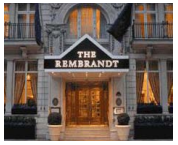
25-27 March 2019 **Ref: 10399**
25-27 September 2019 **Ref: 10522**

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

Programme schedule

Registration and refreshments: 09.00
Day 1: 09.30 17.30
Day 2: 09.00 17.00
Day 3: 09.00 16.30

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 | **info@management-forum.co.uk** | **+44 (0)20 7749 4730**

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 15 February 2019
£1549.00 + VAT= £1858.80 • €2169.00 + VAT = €2602.80

FULL PRICE Book AFTER 15 February 2019
£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

Management Forum in-house training

Coming to Management Forum 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, 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.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

To find out more please, visit: ***management-forum.co.uk***

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.

PLEASE NOTE: Management Forum Ltd 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, Management Forum will refund the registration fee and disclaim any further liability.

For event cancellation policy and T&Cs see our website

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Includes: **Practical and interactive exercises**

MANAGEMENT forum

Advanced Pharmacovigilance

25-27 March 2019 • 25-27 September 2019 London

Key topics to be addressed:

- Audits and expectations – risk-based inspections
- Compliance and drug safety
- Overview of the PSMF in the EU
- Product safety reviews – purpose and function (incorporating the latest EU signal analysis requirements)
- Safety reporting in licensing agreements
- Developing Company Core Safety Information (CCSI) – CIOMS III
- PSURs – timing, content and the DSUR and the latest ICH E2C (2nd revision requirements)
- Implications for safety reporting in global clinical trials
- Risk/benefit determinations
- Risk Management Plans (RMPs)

Expert trainer:
Graeme Ladds, Director, PharSafer

'Excellent course, taught me from A to Z about PV. Content well coordinated to capture audience with different levels of PV experience. Excellent speaker. Highly recommended.'
Suna Horner, HRA Pharma UK & IE Ltd

'It covers a lot of subjects and was a complete course regarding activities in pharmacovigilance. Presentation and speakers were really clear.'
Gwladys Becuwe, Anticipsante

CPD CERTIFIED The CPD Certification Service

Advanced Pharmacovigilance

25-27 March 2019 • 25-27 September 2019, London

Introduction

This three-day course is designed for those with at least two years' knowledge in drug safety and will provide a comprehensive, yet practical assessment of the main regulations required to produce a compliant reporting company.

Benefits of attending

- **Expand** your global safety knowledge
- **Enhance** your team's capabilities and compliance in both the regulations and your company's expectations
- **Help** ensure you build and maintain a quality pharmacovigilance department ready for any pharmacovigilance inspection
- **Participate** in group workshop sessions and discuss how to apply the legislation to ensure compliance, especially to satisfy regulatory inspections
- **Discuss** the implications of Brexit

Expert trainer

Graeme Ladds, Director of PharSafer, has over 25 years' experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1989 as Head of Drug Safety and Medical Information, Graeme went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. The last 13 years have been spent in his consultancy company, PharSafer Associates Ltd. During this time, Graeme 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.

Who should attend?

This course would be of maximum benefit to those safety professionals who are working both in the clinical and post–marketing safety arena including QA for auditing. The course covers very diverse activities within the safety department and would be advantageous to those who have either multifunction responsibilities or medical directors who manage teams in the various disciplines.

In–house TRAINING

Management Forum in-house training

This course is also available in-house and can be tailored to your specific needs. For a **FREE** consultation call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

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

Programme

Day one

Due diligence
- Due diligence on products, companies (partners and acquisitions)
- Due diligence involvement – team composition
- Safety information requirements for due diligence
- Review of safety data (clinical and post-marketing)
- Defining risk in due diligence appraisals

Training for drug safety reporting duties
- Regulations concerning safety training
- Who trains whom and when?
- Training versus job description
- Training records, maintenance and updates
- Role of QA and HR in training

Audits and expectations
- Regulatory expectations in pharmacovigilance audits (risk-based inspections)
- Preparation for the audit
- Records to be available at the audit
- Audit findings/recommendations

Compliance and drug safety
- Basic principles – what will the regulators want to see?
- Measuring compliance
- Quality versus quantity in safety reports
- Future aspects in ensuring efficient compliance
- Quality management under the new EU legislation

The PV System Master File (PSMF)
- The PSMF – purpose and maintenance
- The PSMF annexes
- The PSMF and audits

Interactive exercise: The requirements for a safety department

Implications of Brexit

Day two

Product safety reviews – purpose and function
- The Safety Review Committee (SRC)
- What to look for in signal evaluation under latest EU guidance
- Timings for safety review in clinical and post-marketed products
- Record keeping for safety review meetings
- Serious safety findings – crisis management following new safety findings

Interactive exercise: Designing the requirements for a safety review group

Safety reporting in licensing agreements
- What types of licensing agreements exist?
- What are the EU and FDA Regulations concerning licensing agreements?
- Audits of pharmacovigilance capabilities in licensing partners
- What agreements need to be in place for safety reporting?
- Safety reporting agreements – what needs to be covered?
- Monitoring safety agreements – what happens if it goes wrong?

Developing Company Core Safety Information (CCSI) – CIOMS III
- CIOMS III and CCSI
- Developmental core safety information (DCSI)
- How to determine what to include and what to exclude in DCSI/CCSI
- Are there differences in EU and FDA?
- Maintenance and development of CCSI

Interactive exercise: Should new safety data from a clinical trial be put into core safety information?

PSURs and the revisions in ICH E2C
- Timing for PSURs
- PSUR content and latest format
- Late breaking information and PSUR extensions
- The DSUR

Day three

The EU Clinical Trials Directive
- The principles of the directive
- Implications for safety reporting in global clinical trials
- The SUSAR database
- The EUDRACT database
- The new EU Clinical Trial Regulation

Risk/benefit determinations
- Definitions of risk/benefit – FDA and EU perspective
- Risk/benefit assessments – who does this and where does the information go?
- Safety assessments and risk/benefit – frequency and reporting
- Changes in risk/benefit – how to manage and review existing profiles

Interactive exercise: Reviewing the safety and risk/benefit of a product

Risk Management Plans (RMPs)
- Purpose
- Content
- Monitoring and updating the RMP
- Reporting the RMP

Crisis management within drug safety
- Regulations and guidelines in connection with serious safety issues
- What determines a crisis?
- Communications to regulators – what is required?
- Communications within the company
- What happens next?

Interactive exercise: Deciding how to handle a major crisis within the company

Delegates will be split into groups and present what they need to have in place in order to effectively manage the crisis and look to its resolution.

Close of course