Book before 15 December 2017 and SAVE £100 / €140

Writing RMPs 29 January 2018 (Ref: 10198) • 4 July 2018 (Ref: 10228)
Producing and Maintaining the PSMF 30 January 2018 (Ref: 10227) • 5 July 2018 (Ref: 10229)
An Introduction to REMS 31 January 2018 (Ref: 10201) • 6 July 2018 (Ref: 10230)

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

Venue

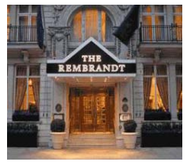
The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44(0)20 7589 8100
www.sarova-rembrandthotel.com

For each course:

Programme schedule for each course

Registration and refreshments:	09.00
Start of course:	09.30
Close of course:	17.00

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

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 15 December 2017
£599.00 + VAT = £718.80 • €839.00 + VAT = €1006.80

FULL PRICE Book AFTER 15 December 2017
£699.00 + VAT = £838.80 • €979.00 + VAT = €1174.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£594.15 + VAT = £712.98 • €832.15 + VAT = €998.58

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

These courses are 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

Book Before 15 December 2017 and SAVE £100 / €140

Three 'must-attend' events for pharmacovigilance professionals

MANAGEMENT forum

Writing Risk Management Plans (RMPs)

29 January 2018 • 4 July 2018 London

Topics to be covered will include:

- An introduction to ICH and EU RMPs - production and maintenance
- Documentation to be supplied to regulators - the process for RMPs
- The EU Templates and their completion - generic and innovator products
- RMPs in other countries

Producing and Maintaining the Pharmacovigilance System Master (PSMF)

30 January 2018 • 5 July 2018 London

Topics to be covered will include:

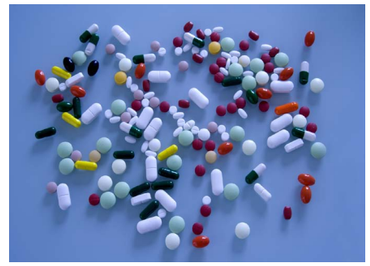
- Production, maintaining and updating the PSMF
- Maintaining the Annexes associated with the PSMF
- Control of the PSMF including the EU QP PV and the XEVMPD
- The PSMF and major changes
- The PSMF audits and inspections

An Introduction to Risk Evaluation and Mitigation Strategies (REMS)

31 January 2018 • 6 July 2018 London

Topics to be covered will include:-

- The background to REMS
- What products qualify for REMS?
- Understand the different categories of REMS
- Discuss their introduction, maintenance and reporting assessments
- Contrast the approach between the US and FDA for a RMP or REMS programme



Expert trainer

Graeme Ladds Pharsafer

Includes: Interactive discussion sessions

CPD CERTIFIED The CPD Certification Service

Writing Risk Management Plans (RMPs)

29 January 2018 • 4 July 2018, London

Understand their relationship to safety reviews; PBRERs/ DSURs; licence submissions (CTD) and their maintenance

Why you should attend

The pharmacovigilance legislation of 2012 requires companies to provide Risk Management Plans (RMPs) and assessments for all new products, whether generic products or new chemical entities. If these are not done correctly this can delay both licensure and sales and damage the company's ability to maximise its products. Maintenance of RMPs is also an important aspect of maintaining compliance.

Who should attend

This course will be relevant for anyone requiring a comprehensive overview of the pharmacovigilance function and duties and may be of particular interest to those who are responsible in pharmacovigilance for any safety assessments and writing such plans including any medical directors who approve such plans. those who work with pharmacovigilance, e.g. regulatory affairs, clinical, sales and marketing, legal, commercial and quality and EU QP PVs that must sign off such documents.

Programme

▶ An introduction to EU RMPs - production and maintenance
- ICH E2E - Risk Management Plans
- EU Module V - Risk Management Plans
- Production of the EU RMP
- Maintenance of the RMP (Safety Reviews; PSURs/DSURs)

▶ Documentation to be supplied to regulatory authorities - the process for RMPs
- Generic RMPs
- RMPs for Innovator products
- Additional documents to supply to the regulators
- Safety reporting timelines for RMPs
- Japan and the USA and RMPs

▶ The EU templates and their completion - generic and innovator products including RMPs in other countries
- The EU generic template
- The EU template for innovator products
- The RMP template in Japan

▶ Practical - completion of sections I - III
- Section I - Information sources and completion
- Section II - Common aspects for risk appraisal from clinical studies
- Section III - The pharmacovigilance plan

▶ Practical - completion of sections IV - VI
- Section IV - Post Authorisation Efficacy Studies
- Section V - Risk minimisation activities
- Section VI - Summary of the RMP

▶ Practical - completion of Annexes
- Annex 1: Interface between RMP and Eudravigilance/EPITT
- Annex 2: Summary of product characteristics (SmPC) and package leaflet
- Annex 3: Worldwide marketing authorisation status by country (including EEA)
- Annex 4: Synopsis of on-going and completed clinical trial programme
- Annex 5: Synopsis of on-going and completed pharmacoepidemiological study programme
- Annex 6: Protocols for proposed and on-going studies
- Annex 7: Specific adverse event follow-up forms
- Annex 8: Protocols for proposed and on-going studies in RMP part IV
- Annex 9: Synopsis of newly available study reports for RMP parts III-IV
- Annex 10: Details of proposed additional risk minimisation activities (if applicable)
- Annex 11: Mock up examples of the material provided to healthcare professionals and patients
- Annex 12: Other supporting data (including referenced material)

Producing and Maintaining the PSMF

30 January 2018 • 5 July 2018, London

Why you should attend

All EU regulatory pharmacovigilance Inspections start with the assessment of the PSMF. The PSMF provides the regulators with not only a detailed assessment of the system but the outputs from that system contained in the Annexes provide an understanding of a company's compliance. This course will provide a practical guide to both producing and maintaining the PSMF to ensure compliance and has been fully revised to include the 2017 update.

Who should attend

This course will be relevant for anyone requiring a comprehensive overview of the pharmacovigilance function and duties, particularly those who are responsible in pharmacovigilance for any safety assessments and writing such plans including any EU QP PVs who approve such documents. Those who work with pharmacovigilance, e.g. regulatory affairs, clinical, sales and marketing, legal, commercial and quality must sign off such documents.

Programme

▶ The content of the PSMF
- The PSMF template
- The detail in the PSMF
- Preparation of the Annexes
- The PSMF log book

▶ The sections of the PSMF
- Section on the EU QP PV
- Sources of safety data
- IT and databases
- Regulatory timeline compliance
- The PSMF processes
- Testing of quality in the PSMF
- The Company Quality System

▶ The Annexe requirements for the PSMF
- The Company Product List
- The EU QP PV list of delegated tasks
- The list of SOPs and procedures
- List of delegated activities to third party partners
- A list of completed audits and schedules
- A list of performance indicators for the PSMF section
- The roles and responsibilities of the EU QP PV
- Master File number and version changes

▶ The PSMF and inspections

▶ Requests for the PSMF

▶ The PSMF and quality

▶ Log books and audit trails

▶ The PSMF post inspection

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 1990 as Head of Drug Safety & Medical Information, Graeme went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. The last thriteen years have been spent in his consultancy and specialist CRO company, PharSafer Associates Ltd. In this role, Graeme has been involved in providing fully outsourced global pharmacovigilance (clinical and post-marketing) for a multitude of different pharma companies, as well as medical information for companies worldwide and in establishing pharmacovigilance in companies, performing audits across Europe, Asia and the USA, SOP and RMP writing, safety database selections, acting as QP for companies, and helping with regulatory inspections.

An Introduction to REMS

31 January 2018 • 6 July 2018, London

Why you should attend

The course will provide insight into the FDA thinking of which products qualify for a Risk Evaluation and Mitigation Strategies (REMS), the different categories of REMS, their introduction and maintenance and the reporting assessments on the REMS.

The course will also briefly look at the approaches between the EU and USA for the same product under an RMP or REMs programme.

Who should attend

This course is applicable for those working in the area of product risk assessment or wanting to learn more about the USA implementation of ICH E2E risk approaches for medicines.

This includes pharmacovigilance personnel working in safety review and risk assessments, QA, clinical personnel and EU QP PVs.

Programme

▶ The background to REMS
- ICH E2E
- PDUFA III
- REMS history

▶ The development of REMS

▶ Products qualifying for REMS

▶ Product specific REMS

▶ The REMS audience
- Identifying the need for a REMS
- REMs and educational material
- REMs and healthcare professionals
- Pharmacy systems under REMS
- Practice settings under REMS

▶ REMS and RMPs
- Clinical Programme Product identified risks
- Differences in REMS and RMPs
- Crossover in REMS and RMPs
- Lifespan of REMS and RMPs

▶ Managing a REMs programme
- Introduction of a REMS
- Assessment of the REMS programme
- Changes and amendments
- Safety reviews and REMS
- REMS and RMPs

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

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