Book Before 21 December 2018 and SAVE £100/€140

Includes: Interactive discussion sessions

MANAGEMENT forum

A Practical Guide to Writing Risk Management Plans (RMPs)

By attending this course you will:

- **Gain** an overview of ICH and EU RMPs - their production and maintenance
- **Clarify** the documentation to be supplied to regulators and the process for RMPs
- **Discuss** the EU Templates and their completion - generic and innovator products
- **Understand** the relationship with PSMFs to safety reviews; PBRERs/DSURs and licence submissions

28 January 2019
2 July 2019
LONDON

'Very well presented and in-depth description on each section. I enjoyed the real-life examples - easier to relate and apply to my own circumstances.'

Claire McLaughlin, Kyowa Kirin International

Producing and Maintaining the Pharmacovigilance System Master File (PSMF)

By attending this course you will:

- **Understand** the regulatory requirements for the PSMF
- **Gain** an overview of the key issues in producing, maintaining and updating the PSMF
- **Learn** about the roles of the QPPV and the PSMF
- **Discuss** the PSMF and Regulatory Inspections

29 January 2019
3 July 2019
LONDON

'Interesting, fun speaker; good stories that are easy to relate to.'

Jill Brogaard, H Lundbeck A/S

Expert trainer for both courses:

Graeme Ladds PharSafer

CPD CERTIFIED The CPD Certification Service

A Practical Guide to Writing Risk Management Plans (RMPs)

28 January 2019 • 2 July 2019, London

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

Why you should attend

In the EU, all companies are required to provide Risk Management Plans (RMPs) for every new product, whether generic products or new chemical entities, and these RMPs must also be modified and updated throughout the lifetime of a medicine.

This course will provide an invaluable overview on writing and maintaining Risk Management Plans, with practical advice to ensure you achieve regulatory compliance. This course has been fully revised to include the latest updates.

Who should attend?

This course will be relevant for those working in pharmacovigilance who are involved with writing Risk Management Plans, including Medical Directors/QPPVs who approve such plans. It will also be of interest to those who work with pharmacovigilance, eg in regulatory affairs, clinical, sales and marketing, legal, commercial and quality.

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)

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

Producing and Maintaining the PSMF

29 January 2019 • 3 July 2019, London

Why you should attend

All EU regulatory pharmacovigilance inspections start with the assessment of the Pharmacovigilance System Master File (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 latest updates.

Who should attend?

This course will be relevant for anyone working in pharmacovigilance requiring a comprehensive overview of the PSMF, including QPPVs and those responsible for safety assessments. It will also be of interest to those who work with pharmacovigilance, eg in regulatory affairs, clinical, sales and marketing, legal, commercial and quality.

Programme

Introduction and background to the PSMF

- What is the role of the PSMF?
- When to submit the PSMF
- Subcontracting pharmacovigilance activities
- Regulatory requirements for the PSMF
- Responsibilities of the MAH

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 Annex 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 (audit trail)

The PSMF and inspections

- The PSMF and inspection findings
- Regulatory authority requests to view the PSMF
- Transfer of responsibility for a pharmacovigilance system to the QPPV
- Notifying the QPPV of changes to the PSMF
- PSMF responsibilities with shared marketing authorisation holders
- Change control, logbook, versions and archiving
- Audit trails and the PSMF
- The PSMF post-inspection

Expert trainer for both courses

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 13 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. He has also established pharmacovigilance systems in companies where he has been involved with performing audits worldwide, SOP and RMP writing and safety database selection as well as acting as QP and helping with regulatory inspections.

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A Practical Guide to Writing Risk Management Plans (RMPs)

28 January 2019 (Ref: 10321) • 2 July 2019 (Ref: 10500) To book online go to: **management-forum.co.uk/2193**

Producing and Maintaining the PSMF

29 January 2019 (Ref: 10322) • 3 July 2019 (Ref: 10501) To book online go to: **management-forum.co.uk/2194**

Save an additional £100/€140 if you book both courses

Dates and venue

Writing Risk Management Plans (RMPs)

28 January 2019 **Ref:10321**
2 July 2019 **Ref:10500**

Producing and Maintaining the PSMF

29 January 2019 **Ref: 10322**
3 July 2019 **Ref: 10501**

The Cavendish Hotel, 81 Jermyn Street, London SW1 6JF, Tel: +44 (0)20 7930 2111
(Note: Entrance via Duke Street)

Programme schedule for both courses

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

Accommodation

When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price please mention that you are attending the Management Forum seminar when booking your accommodation.

Web: *www.thecavendish-london.co.uk/*
Email: *enquiry.cavendish@the-ascott.com*

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

Three ways to book

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£599.00 + VAT = £718.80 • €839.00 + VAT = €1006.80

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£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

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Management Forum in-house training

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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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