Book before 15 March 2019
and SAVE £200/€280

Pharmacovigilance QMS and Inspection Preparation

To book online go to: management-forum.co.uk/2385 W

Dates and venue

9-10 May 2019 **Ref: 10458**
11-12 November 2019 **Ref: 10523**

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

Programme schedule

Registration and refreshments: 09.00

	Day one	Day two
Start	09.30	09.00
Close	16.45	16.45

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.

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

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 March 2019
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE Book AFTER 15 March 2019
£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 + VAT = £1528.98 • €1784.15 + VAT = €2140.98

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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Book Before 15 March 2019 and SAVE £200/€280

Includes: Practical and interactive sessions

MANAGEMENT forum

Pharmacovigilance QMS and Inspection Preparation

9-10 May 2019 • 11-12 November 2019 London

Benefits of attending:

- **Understand** pharmacovigilance Quality Management Systems (QMS) and risk-based audits
- **Learn** the importance of Key Performance Indicators (KPIs) in your QMS
- **Ensure** compliance with assessments of risk and your CAPA and preventative actions
- **Discuss** pharmacovigilance inspections and QMS activities

Expert trainer:

Graeme Ladds

Director, PharSafer Associates Ltd

'A very knowledgeable presenter in QA and particularly in PV. The content was rich and touched on all areas in great detail.'

Maria Calvo Subirats, Ferrer Internacional

CPD CERTIFIED The CPD Certification Service

Pharmacovigilance QMS and Inspection Preparation

9-10 May 2019 • 11-12 November 2019, London

Why should you attend?

Since the introduction of the new pharmacovigilance legislation in the EU, QMS and self-audits have become an increasingly important topic. Companies have been challenged by regulators to implement risk-based audits where continual improvement of processes, systems and compliance to regulations needs to be demonstrated. This is required from the top of the company organisation in all areas of regulatory activity from clinical, pharmacovigilance, sales and marketing, IT and medical services.

This course is designed to help in both the assessments of risk and the whole CAPA and preventative action elements.

Who should attend?

QA representatives, EU QPPV and all working in pharmacovigilance, regulatory, clinical and administrators responsible for the management of the CAPA systems.

Expert trainer

Graeme Ladds, Director of PharSafer, has over 26 years' experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1990 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 and specialist CRO company, PharSafer Associates Ltd. During this time, Graeme has been involved in providing fully outsourced globalpharmacovigilance (clinical and post-marketing) 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.

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

Group discounts are available. Please contact customer services on +44 (0) 20 7749 4730 or email info@management-forum.co.uk for more information

Programme

Day one

09:00 ▶ **Registration and refreshments**

09:30 ▶ **Introduction and welcome**

09:40 ▶ **The audit basics**
- The purpose of an audit
- Qualifications of the auditor
- The audit SOP and design
- The difference between audits and inspections
- Audit planning and risk assessments

10:30 ▶ **The legislation and audits**
- The requirements to perform company audits
- In-house versus external audits
- What needs to be audited
- Which departments need auditing for safety

11.15 ▶ **Refreshments**

11.35 ▶ **QMS**
- QMS design
- Quality cycles – expectations and deviations
- Quality risk assessments
- KPIs
- Quality failings and corrections

12.45 ▶ **Lunch**

13.45 ▶ **QMS and the audit report**
- The audit scope and conduct
- The audit report content
- The grading of audit reports
- Corrective action plans (root cause analysis)
- Re-audits

15.00 ▶ **Refreshments**

15.20 ▶ **Workshop session**
You will be asked to design the QMS for a safety department that has recently been audited. You will need to devise a plan based on any risk elements and audit findings identified and look at designing a QMS approach with KPIs.

16.45 ▶ **End of day one**

Day two

09:00 ▶ **Introduction to PV inspections**
- Background
- Purpose – design
- Roles and responsibilities of the licence holder
- Conduct of regulatory inspections

10:15 ▶ **Risk-based inspections**
- Defining risk
- Routine and for-cause inspections
- Triggers for an inspection
- Who should attend the inspection?

11.00 ▶ **Refreshments**

11.15 ▶ **The pharmacovigilance inspection cycle**
- Pre-inspection questionnaires
- Site visits and telephone audits
- Results and CAPAs
- Inspection follow-up questionnaires
- Follow-up inspections

12.30 ▶ **Lunch**

13.30 ▶ **Workshop session**
You will be presented with a series of findings from a regulatory inspection. You will have to look at the findings and work out priorities, devise root cause analyses and provide detailed corrective and preventative action plans which will include QMS activities.

15.00 ▶ **Refreshments**

15.20 ▶ **Common findings from regulatory inspections**
- Grades of findings (and how to grade findings)
- How to grade findings in the same PV area
- Allied findings in other departments
- KPIs versus legislation
- Variations in major authority inspections

16.30 ▶ **Final discussion session**

16.45 ▶ **End of course**

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