ADVANCED PHARMACOVIGILANCE

30 September, 1 & 2 October 2013, Conf. No. A9-4213

W MANAGEMENT FORUM

Application to Register

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To Register

+44 (0) 1483 730008

Management Forum Ltd

www.management-forum.co.uk

E-mail: registrations@management-forum.co.uk

If you have NOT received confirmation seven days after registering, please contact Registration Department.

Registration Information

Dates

30 September 2013	Start: 09.30 – Finish: 17.00
Drinks Reception	Start: 17.00 – Finish: 18.00
1 October 2013	Start: 09.00 – Finish: 17.00
2 October 2013	Start: 09.00 – Finish: 16.30

Registration & Coffee

30 September 2013 09.00

Venue and Accommodation

The Rembrandt Hotel, 11 Thurloe Place, London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax:+44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate. **All bookings should be made directly with the hotel or online at *www.sarova.com/rembrandt*, quoting promo code 'manforum'.**

Directions

Opposite V&A Museum. Nearest underground station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee

£1,700 + VAT if applicable. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. A9-4213

Discounted Rates

Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request

Cancellation Policy:

Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
NB: Cancellations must be received in writing by *registrations@management-forum.co.uk*
Management Forum reserves the right to cancel/ alter the programme, the speakers, the date or venue. If an event is cancelled Management Forum is not responsible for airfare, hotel or other costs incurred by registered delegates.

For Promotional Opportunities email: robert@management-forum.co.uk

MANAGEMENT FORUM LTD., 98-100 Maybury Road,Woking, Surrey GU21 5JL, UK
Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008
Website: www.management-forum.co.uk

Fully Updated to include the New European Pharmacovigilance Legislation

MANAGEMENT FORUM

ADVANCED PHARMACOVIGILANCE

A 3 day Advanced Level Course

Key Topics to be covered:

- Due Diligence
- Training for Drug Safety - Reporting Duties, Audits and Expectations – Risk based Inspections
- The DDPS retirement and the new PV Master file in the EU
- Compliance and Drug Safety*
- Product Safety Reviews – Purpose and Function (Incorporating the new EU Signal Analysis Requirements)
- Developing Company Core Safety Information – CIOMS III
- Safety Reporting in Licensing Agreements
- PSURs – Timing, Content and the DSUR* and the new ICH E2C (2nd Revision requirements)
- Implications for Safety Reporting in Global Clinical Trials
- Risk/Benefit Determinations
- Risk Management Plans
- Crisis Management within Drug Safety

*(including expectations from the new legislation)

With:

Graeme Ladds, Director, PharSafer

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CPD CERTIFIED
The CPD Certification Service

Comments from previous delegates include
"Extremely interesting topics discussed, clear presentations, well delivered "
"Very informative and really helpful"
"Perfect course, clearly explained with lots of examples"

Register on-line at www.management-forum.co.uk
or telephone +44 (0)1483 730071, fax 44 (0) 1483 730008

30 September, 1 & 2 October 2013
The Rembrandt Hotel, London

INTRODUCTION

This course is designed for those with at least 2 years worth of knowledge in Drug Safety and will provide a comprehensive, yet practical assessment of the main Regulations required to produce a compliant reporting Company.

BENEFITS IN 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.

COURSE LEADER

Graeme Ladds, Director of PharSafer, has over 22 years experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1989 as Head of Drug Safety & Medical Information, Graeme went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. The last ten 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.

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all **MANAGEMENT FORUM** seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

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sarah@management-forum.co.uk

Programme

Day 1

Due Diligence
- Due Diligence on products, Companies (Partners & 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 and 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 Master File and the DDPS
- The PV Master File
- The PV Master File – purpose and maintenance
- The DDPS – What happens now
- Transition from DDPS to PV Master File

Interactive Exercise: Designing the Requirements for a Safety Department and Drug Safety

Delegates will be split into groups and present what they need a safety department to be capable of performing. A scenario will be presented to the delegates regarding a product situation and they must decide on the best course of action.

Day 2

Product Safety Reviews – Purpose & Function
- The Safety Review Committee
- What to look for in signal evaluation under new 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

Delegates will be split into groups and present what they need a safety review to be capable of performing, who they need to link with and what decision making capabilities they should have. A scenario will be presented to the delegates regarding a product situation and they must decide on the best course of action.

Safety Reporting in Licensing Agreements
- What types of Licensing Agreements exist?
- What are the EU & 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 – CIOMS III
- CIOMS III & Core Safety Information
- Developmental Core Safety Information (DCSI)
- How to determine what to include, what to exclude in DCSI/CCSI
- Are there differences in EU and FDA
- Determinations of inclusion in CCSI
- Maintenance & development of CCSI

Interactive Exercise: Deciding whether New Safety Data presented from a Clinical Trial should be put into Core Safety Information

Discussion will also include how does this leave the new safety profile of the product?

PSURs and the new revisions in ICH E2C
- Timing for PSURs
- PSUR Content – and new format
- Late breaking information and PSUR extensions
- The DSUR

Day 3

The EU Clinical Trials Directive
- The Principles of the Directive
- Implications for Safety Reporting in Global Clinical Trials
- The SUSAR Database
- The EUDRACT Database

Risk/Benefit Determinations
- Definitions of Risk/Benefit – FDA and EU perspective (including the new 2012 legislation)
- 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 of a Product

Delegates will be split into groups and present what they think needs to happen with the safety information presented on their product and what does this mean for the Benefit/Risk with the product.

Risk Management Plans (including new EU requirements 2012)
- Purpose
- Content
- Monitoring and updating the RMP
- Reporting the RMP

Crisis Management within Drug Safety
- Regulations & 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.