MANAGEMENT FORUM

PHARMACOVIGILANCE

A BASIC TRAINING COURSE FOR THOSE WORKING ON DRUG SAFETY MONITORING IN THE EU, USA AND JAPAN

Celebrating 30 Years

EARLY BOOKING RECOMMENDED

Key topics to be addressed at this conference

- Principles of Pharmacovigilance and Data Resources
- Risk Management and the development of the Pharmacovigilance plan
- Causality Assessment: Clinical Diagnosis of Adverse Events
- Pharmacoepidemiological Studies
- PSURs and the link with DSURs and the EU risk management plan
- Pro-active Pharmacovigilance Pre- and Post Marketing
- Pharmacovigilance Regulations (clinical trials & post marketing) including new EU Pharmacovigilance Legislation
- Risk/Benefit Analysis
- Drug Surveillance in countries outside Europe
- Post-marketing Surveillance: Observational Cohort Studies
- Global pharmacovigilance regulations and systems and their link with EU pharmacovigilance
- Practical Pharmacovigilance Workshop

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Chairmen:

Day One: **Professor Saad Shakir** Director Drug Safety Research Unit, UK
Dr Barry Arnold EU Qualified Person for Pharmacovigilance, AstraZeneca R&D, UK

Day Two: **Dr Barry Arnold** EU Qualified Person for Pharmacovigilance, AstraZeneca R&D, UK

Day Three: **Dr Glyn Belcher** Consultant, PV Consultancy Ltd

CPD CERTIFIED
The CPD Certification Service
Collective Mark

16-18 December 2013
The Rembrandt Hotel, London

WHY YOU SHOULD ATTEND

This Management Forum course aims to provide basic training for those concerned with pharmacovigilance. New entrants as well as experienced operators in drug safety monitoring will benefit from the mixture of scientific knowledge and practical guidance. In addition, detailed information will be provided on regulatory developments in pharmacovigilance in Europe, the USA, and Japan.

WHO SHOULD ATTEND

This three-day introductory course is aimed at personnel in research and development departments, adverse reaction monitoring units, regulatory affairs and registration departments; pharmaceutical physicians and drug safety officers. It will also be of direct benefit to all those who are involved and interested in the daily practice of pharmacovigilance.

ATTENDANCE LIMITED TO 40

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.

FORTHCOMING EVENTS

For a full list of forthcoming conferences and seminars please visit our website at:
www.management-forum.co.uk
You may make a registration and request a brochure on-line.

CHAIRMEN

Dr Barry Arnold
EU Qualified Person for Pharmacovigilance
AstraZeneca R&D, UK

Dr Glyn Belcher
Consultant, PV Consultancy Ltd

Professor Saad Shakir
Director, Drug Safety Research Unit, UK

SPEAKERS

Dr John Parkinson
Director, Clinical Practice Research
Datalink - MHRA, UK

Dr John Talbot
Senior Lecturer at University of Hertfordshire

Dr Lynda Wilton
Consultant, Education Division Symogen
UK Ltd

Dr Andrew Thomson
Head of Epidemiology in the Vigilance and Risk Management of Medicine, MHRA

A Certificate of Attendance for Professional Development will be given to each participant who completes the course

PROGRAMME

Day One — 16 December 2013

CHAIRMAN: PROF. SAAD SHAKIR

09.30 ▶ Principles of Pharmacovigilance and Data Resources
- Basic principles of monitoring drug safety
- An overview of methodology
- Data resources available for monitoring and evaluating drug safety
- Responding to drug safety signals

Professor Saad Shakir

10.30 ▶ Coffee

10.45 ▶ Risk Management
- Basic principles
- Proactive strategies
- Development of the pharmacovigilance plan

Professor Saad Shakir

11.30 ▶ Causality Assessment: Clinical Diagnosis of Adverse Events
- The principles of causality assessment with practical examples
- Medical evaluation of individual reports of adverse events
- Strategies for follow up

Professor Saad Shakir

12.30 ▶ Discussion

12.45 ▶ Lunch

CHAIRMAN: DR BARRY ARNOLD

14.00 ▶ Pharmacoepidemiological Studies - Basic Designs, Strengths, Weaknesses and Examples
- Real World Data is the King
- Randomisation in the real world
- Drugs and devices- its all “exposure”
- Tracking all Patients?

Dr John Parkinson

15.15 ▶ Discussion

15.30 ▶ Tea

Pharmacovigilance Regulations

15.45 ▶ Session I: Regulatory Framework
- Overview of European regulatory framework, including new EU Pharmacovigilance Legislation
- Inspections & penalties for non-compliance
- Practical application of definitions

Dr Barry Arnold

17.15 ▶ End of Day One and Drinks Reception

PROGRAMME

Day Two — 17 December 2013

CHAIRMAN: DR BARRY ARNOLD

09.00 ▶ Pro-active Pharmacovigilance Pre- and Post Marketing
- Anticipating drug safety issues in development
- What specific and non-specific safety monitoring should be done?
- Handling safety signals in development
- Differences between pre-marketing studies and post-marketing experience
- Planning pharmacovigilance for the marketed product

Dr John Talbot

10.00 ▶ Discussion

10.10 ▶ Risk/Benefit Analysis
- Standardising risk/benefit analysis
- Putting risks into context
- Taking effective action and communicating effectively

Dr Andrew Thomson

11.00 ▶ Discussion

11.15 ▶ Coffee

11.30 ▶ Where are we now with PSURs (PBRERs)
- Evolution of the PSUR, PBRER and DSUR GVP Module VII and ICH E2C (R2)
- What do we need to submit and when is it required?
- Practical aspects of compiling PBRERs
- The link between the DSUR, RMP, PBRER, and Core Safety Information

Dr John Talbot

12.30 ▶ Discussion

12.45 ▶ Lunch

14.00 ▶ Session II: Clinical Trial ADR reporting requirements
- General requirements
- Expedited reports
- Development Safety Update Reports (DSURs)

Dr Barry Arnold

15.30 ▶ Tea

15.45 ▶ Session III: European Post-marketing Pharmacovigilance Regulations
- General requirements
- Pharmacovigilance & Quality Systems
- QPPV
- Expedited reports
- Periodic reports
- Post-authorisation Safety Studies
- Related requirements

Dr Barry Arnold

16.45 ▶ Discussion

17.00 ▶ End of Day Two

PROGRAMME

Day Three — 18 December 2013

CHAIRMAN: DR GLYN BELCHER

09.00 ▶ Drug Surveillance in countries outside Europe
- US culture
- NDA and IND safety reporting
- Inspections
- Japan culture
- Post-marketing safety surveillance programmes in Japan
- Pharmacovigilance in developing countries

Dr Glyn Belcher

10.00 ▶ Discussion

10.15 ▶ Post-marketing Surveillance: Observational Cohort Studies
- The significance of monitoring events v suspected ADRs
- Principles of observational techniques used for event monitoring
- Detecting signals in observational cohort studies

Dr Lynda Wilton

11.00 ▶ Coffee

11.20 ▶ Continuation of Lecture

Dr Lynda Wilton

12.00 ▶ Introduction to risk management plans from the industry point of view
- The details of the EU risk management plan and how successfully to write one
- Assessment of risk management plans by EU regulators
- Updating risk management plans and the link with the new PSUR Global risk management plans
- What to consider concerning operationalisation of risk management plans
- A real world case example of the development of an EU risk management plan

Dr Glyn Belcher

13.00 ▶ Discussion

13.15 ▶ Lunch

14.15 ▶ Practical Pharmacovigilance Workshop

As requested by previous participants in this course, this session will comprise a practical case study with valuable hands-on experience covering:
- Handling an important safety alert from regulators
- Assessment of risk
- Determining measures to respond to previously unidentified risks
- Continuing assessment and communication of risk benefit

Dr Lynda Wilton & Dr Glyn Belcher

16.00 ▶ End of conference and Tea

DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future

MANAGEMENT FORUM

PHARMACOVIGILANCE

16-18 December 2013
Conf. No. A12-1013

Application to Register

Please PRINT your details:

Title ..... First Name.....
(Dr, Mr, Mrs, etc)
Family name .....
Position .....
Department.....
Company .....
Company VAT No. .....
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Substitutions may be made at any time at no extra charge

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Expiry date...../.....

☐ Cheque enclosed payable to Management Forum Limited

☐ Bank transfer on receipt of invoice **W**

To Register

+44 (0) 1483 730008
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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 **16-18 December 2013**

Times	**16 December 2013**	**Start 09.30 – Finish 17.15**
	Drinks Reception	**Start 17.15 - Finish 18.15**
	17 December 2013	**Start 09.00 – Finish 17.00**
	18 December 2013	**Start 09.00 – Finish 16.00**

Registration & Coffee
16 December 2013 **09.00**

Venue & 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
£1,675 + VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. A12-1013

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 receive 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.

Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact **Robert Sinclair**
(email: robert@management-forum.co.uk)