PHARMACOVIGILANCE

Application to Register

1-3 December 2014
Conf. No. A12-1014

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To Register

+44 (0) 1483 730008
Management Forum Ltd, 98-100
Maybury Road,Woking, Surrey GU21 5JL, UK
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 **1-3 December 2014**

Times

1 December 2014	**Start 09.30 – Finish 17.15**
Drinks Reception	**Start 17.15 - Finish 18.15**
2 December 2014	**Start 09.00 – Finish 17.00**
3 December 2014	**Start 09.00 – Finish 16.00**

Registration & Coffee
1 December 2014 **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
£1,750 + 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. A12-1014

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)

MANAGEMENT FORUM LTD, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK
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MANAGEMENT FORUM

PHARMACOVIGILANCE

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

EARLY BOOKING RECOMMENDED

Key topics to be addressed at this conference

- Principles of Pharmacovigilance and Data Resources
- Risk Management and Risk Minimisation
- Causality Assessment: Clinical Diagnosis of Adverse Events
- PASS and PAES studies
- Regulatory Framework
- European Post-Marketing Pharmacovigilance Regulations
- Pharmacoepidemiological Studies
- Evolution of PSURs, PBRERs DSURs
- Pro-active Pharmacovigilance Pre- and Post-Marketing
- Clinical Trial ADR reporting requirements
- Risk/Benefit Analysis
- Drug Surveillance in countries outside Europe
- Post-marketing Surveillance: Observational Cohort Studies
- Introduction to Signal detection
- Introduction to Risk Management plans
- Practical Pharmacovigilance Workshop

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Chairmen:

Day One: **Professor Saad Shakir** Director, Drug Safety Research Unit, UK
Shelley Ghandi Director, Pharmacovigilance & Drug Safety, NDA Regulatory Science Ltd

Day Two: **Dr John Talbot** Senior Lecturer at University of Hertfordshire
Dr John Parkinson CPRD, Consultant Expert

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

1-3 December 2014
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 Glyn Belcher
Consultant, PV Consultancy Ltd

Shelley Gandhi
Director, Pharmacovigilance & Drug Safety, NDA Regulatory Science Ltd.

Dr John Parkinson
CPRD, Consultant Expert

Professor Saad Shakir
Director, Drug Safety Research Unit, UK

Dr John Talbot
Senior Lecturer at University of Hertfordshire

SPEAKERS

Carol Markwell
Drug Safety Solutions Ltd, UK

Dr Lynda Wilton
Consultant, Education Division Symogen UK Ltd

Speaker from MHRA TBC

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

PROGRAMME

Day One — 1 December 2014

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 and Risk Minimisation: Basic Principles
- Basic principles
- Proactive strategies
- Principles of risk minimisation
- PASS and PAES studies

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: SHELLEY GANDHI

14.00 ▶ Regulatory Framework
- Overview of European regulatory framework, including new EU pharmacovigilance legislation
- Implications for global environment - the links to ICH and CIOMs recommendations
- Inspections and penalties for non-compliance
- Practical applications of definitions

Shelley Gandhi

15.15 ▶ Tea

15.45 ▶ European Post-Marketing Pharmacovigilance Regulations

Overview of requirements which will include:
- The role of Pharmacovigilance Risk Assessment Committee
- Quality Management Systems and the Pharmacovigilance System Master File (PSMF)
- QPPV
- Expedited Reporting solicited vs spontaneous
- Periodic reports and Signal Management
- Risk Management Plans and Risk Minimisation
- Post Authorisation Safety and Efficacy studies (PASS/PAES)
- Additional Monitoring
- Pharmacovigilance Inspections/audit
- **Public hearing**

Shelley Gandhi

17.15 ▶ End of Day One and Drinks Reception

PROGRAMME

Day Two — 2 December 2014

CHAIRMAN: DR JOHN TALBOT

09.00 ▶ Pro-active Pharmacovigilance Pre- and Post-Marketing
- Anticipating drug safety issues in development of small molecules and biologics
- What specific and non-specific safety monitoring should be done?
- Handling safety signals in development
- Differences between pre-marketing studies and post-marketing experience

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

Speaker from MHRA – TBC

11.05 ▶ Discussion

11.15 ▶ Coffee

11.30 ▶ Clinical Trial ADR reporting requirements
- ICH E2A and General requirements
- Expedited reports
- EU Clinical Trials Directive and Detailed guidance (CT-3)
- US IND Requirements
- Development Safety Update Reports (DSURs)

Dr John Talbot

12.35 ▶ Discussion

12.45 ▶ Lunch

CHAIRMAN: DR JOHN PARKINSON

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

15.30 ▶ Tea

15.45 ▶ Where are we now with PSURs (or PBRERs)?
- Evolution of the PSUR, PBRER and DSUR
  - ICH E2C, Volume 9A, GVP Module VII and ICH E2C (R2)…
- What do we submit now and when is it required?
- Practical aspects of compiling PSURs
- The link between DSURs, RMPs, PSURs, and Core Safety Information

Carol Markwell

16.45 ▶ Discussion

17.00 ▶ End of Day Two

PROGRAMME

Day Three — 3 December 2014

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 ▶ Introduction to Signal Detection
- Definitions of signals
- Regulatory guidances on signal detection by industry and regulators
- Resources for signal detection
- Quantitative v qualitative signal detection

Dr Glyn Belcher

11.00 ▶ Coffee

11.20 ▶ Post-marketing Surveillance: Observational Cohort Studies
- Monitoring events v monitoring ADRs
- Using observational cohorts for signal detection v signal clarification (examples of Prescription Event Monitoring and other studies)
- Pitfalls and strengths of observational studies

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