

NEW PHARMACOVIGILANCE LEGISLATION

13 March 2012, Conf. No. A3-4112



Application to Register Please PRINT your details:

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Management Forum Ltd
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E-mail: registrations@management-forum.co.uk

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

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
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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

Registration Information

Dates
13 March 2012
Start: 09.30 – Finish: 17.00

Registration & Coffee
13 March 2012 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_rebrandt@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. Map available on Website under Hotels and Venues.

Fee
£575 + 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. A3-4112

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.
In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.

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

NEW PHARMACOVIGILANCE LEGISLATION – DIRECTIVE 1235/2010 & 2010/84 JULY 2012 – ALL CHANGE FOR EUROPE



Are you Prepared for the New Legislation?

Benefits of Attending:

- Gain an Invaluable Overview of the New European Legislation
- Discover what Key Areas of Pharmacovigilance Activities will be Affected
- Understand the Impact of the Legislation and what you will need to do to Implement in your Company
- Discuss the Enforcement of the Legislation
- Learn about the Different National Variations

With

Graeme Ladds, Director PharSafer

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You can register online at www.management-forum.co.uk or by phone on +44 (0)1483 730071, fax 730008



13 March 2012
The Rembrandt Hotel, London

WHY SHOULD YOU ATTEND

Not since the introduction of Volume IXa in January 2007 has there been a more dramatic revision of Pharmacovigilance in Europe. The introduction Nationally of the new legislation in July 2012 will radically alter many areas of Pharmacovigilance practice in Europe and require a whole set of new and revised Company procedures and training to accommodate the new requirements in order to remain compliant.

WHO SHOULD ATTEND

This course will be of particular benefit to EU QPs / Deputy of Pharmacovigilance; Quality Assurance; Compliance; Pharmacovigilance Managers; Regulatory and Global Heads of Pharmacovigilance.

It will also be of interest to anyone requiring an overview of this important new legislation.

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.

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

COURSE TUTOR

Graeme Ladds, Director of PharSafer, has over 16 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 two 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

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.

IN-HOUSE TRAINING

If you would like to discuss running this or any other course on an in-house basis, please contact Sarah Spanswick at sarah@management-forum.co.uk

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

Programme

- 09.30** ➤ **Introduction & Welcome**
➤ **The Legislation Outline for 1235/2010 & 2010/84**
- Impact on current legislation
 - Enforcement of new legislation
 - National variations
- 10.00** ➤ **The impact on ICSR Safety Reporting in Europe**
- Changes to expedited reporting
 - Compliance monitoring
 - Regulatory Quality Assessments
 - Electronic versus Paper reporting
- 11.15** ➤ **Coffee**
- 11.30** ➤ **PSURs and DSURs**
- Changes for EU PSUR submissions
 - The DSUR vs PSUR
 - Clinical Annual Reports and Post-Marketing Periodic Reports
 - The DSUR and Risk Management Plans
- 13.00** ➤ **Lunch**
- 14.00** ➤ **The PV Master File**
- The PV Master File – Purpose and Maintenance
 - The DDPS – What happens now
 - Transition from DDPS to PV Master File
- 15.15** ➤ **Tea**
- 15.35** ➤ **Other major changes in new legislation**
- Literature searching
 - The role of the EU QP PV & Country Representatives
 - Risk Management Plans
 - PSURs for Generic products
 - Risk based PV Inspections
- 16.45** ➤ **Final Discussion**
- 17.00** ➤ **Close of Meeting**