# DRAFTING AND MANAGING PHARMACEUTICAL SAFETY DATA EXCHANGE AGREEMENTS

**14 May 2015, Conf. No L5-5115**

MANAGEMENT FORUM

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**For Promotional Opportunities email:**
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Registration Information

**Dates**
14 May 2015
Start: 09.15 – Finish: 17.00

**Registration & Coffee**
14 May 2015 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**
**£598 & 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. L5-5115**

**For Cancellation Policy and T&Cs see website**
NB: Cancellations must be received in writing by ***registrations@management-forum.co.uk***

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To Register

If you have NOT received confirmation seven days after registering please contact ***registrations@management-forum.co.uk***

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MANAGEMENT FORUM

# DRAFTING AND MANAGING PHARMACEUTICAL SAFETY DATA EXCHANGE AGREEMENTS

## FOR THOSE RESPONSIBLE FOR THE PHARMACOVIGILANCE ASPECTS OF COMMERCIAL AGREEMENTS

**6 CPD HOURS**

## Topics to be covered at this seminar:

- Commercial arrangements in the pharmaceutical industry
- Contract basics
- Regulatory requirements
- Key pharmacovigilance terms for commercial agreements
- Key terms in co-marketing and distribution agreements
- Key terms in co-promotion agreements, arrangements with vendors and service providers
- Audit and inspection findings

Speakers:

**Christine Bendall** Pharview Ltd
**Margaret Walters** Merck Sharp & Dohme Ltd

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CPD CERTIFIED
The CPD Certification Service

**14 May 2015**
**The Rembrandt Hotel, London**

## BENEFITS OF ATTENDING

Ensuring the inclusion of key pharmacovigilance-relevant terms in agreements and monitoring compliance with them can be challenging, but is essential for compliance with current regulatory requirements relating to medicinal products.

This seminar will address the key regulatory requirements relating to pharmacovigilance and discuss how to ensure that they are taken into account in various types of commercial arrangements. The emphasis will be on identifying the key terms needed in different types of agreement with a view to ensuring regulatory compliance and on a practical approach to drafting.

## WHO SHOULD ATTEND?

Personnel involved in negotiating, preparing and managing commercial agreements of various types (e.g. between co-marketers and with distributors, vendors and service providers) where the inclusion of pharmacovigilance terms and obligations is needed, including those working in Safety, Commercial, Regulatory Affairs and Legal departments.

**This seminar merits 6 hours CPD and may also be relevant training under the IPReg CPD self-accreditation scheme**

## SPEAKERS

***Christine Bendall*** is a solicitor (non-practising) and works as a regulatory consultant and auditor with a particular focus on pharmacovigilance and research. She has specialised in the law relating to the healthcare industry and the regulation of medicinal products since 1989.

***Margaret Walters*** joined MSD in Drug Safety in 1987 and is currently the MSD Deputy EU Qualified Person for Pharmacovigilance (QPPV) and Director of the UK based Office of the EU QPPV.

**Reserve your place at the course by registering online now at www.management-forum.co.uk or by fax +44 (0)1483 730008**
**Any questions? e-mail *sarah.packham@management-forum.co.uk***

## DOCUMENTATION

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

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

# Programme

**09.15** ▶ **Welcome and introduction**

**09.30** ▶ **Types of commercial arrangement in the pharmaceutical industry**
- Co-marketing
- "Distribution"
- Co-promotion
- Vendors and service providers
- Other

**10.00** ▶ **Contracts – the basics**
- Is there a contract - the principles of offer and acceptance
- Establishing the parties
- The structure of agreements
- Boiler plate clauses
- Review and amendment
- Termination
- Remedies
- Appendices and cross references

**10.30** ▶ **Regulatory requirements and guidance on pharmacovigilance relevant to commercial agreements – ICH regions**

**11.15** ▶ **Coffee**

**11.30** ▶ **Key considerations in negotiating, drafting and managing agreements**
- SOPs – content and compliance
- Creation, use and adaptation of templates
- Introducing pharmacovigilance matters during contract negotiations
- Allocating responsibilities
- Multiple agreements and parties
- Managing agreements following signature
- Details for the PSMF

**12.00** ▶ **Key pharmacovigilance terms for commercial agreements - overview**
- Terminology
- Clarifying the roles of the parties
- Describing the obligations of the parties
- Exchange of data
- Regulatory submissions
- Other obligations

**12.45** ▶ **Lunch**

**13.45** ▶ **Discussion and review of Key Clauses: co-marketing and distribution agreements**

**15.00** ▶ **Tea**

**15.20** ▶ **Discussion and review of Key Clauses: co-promotion agreements, arrangements with vendors and service providers**

**16.00** ▶ **Common problems, audit and inspection findings**

**16.45** ▶ **Q&A**

**17.00** ▶ **Close**