**Signal Detection and Regulatory Expectations**

*To book online go to: management-forum.co.uk/2122*

### Dates and venue

<table>
<thead>
<tr>
<th>Period</th>
<th>Ref.</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-6 May 2020</td>
<td>10817</td>
<td>The Rembrandt Hotel, London</td>
</tr>
<tr>
<td>2-3 November 2020</td>
<td>10818</td>
<td>The Rembrandt Hotel, London</td>
</tr>
</tbody>
</table>

### Programme schedule

<table>
<thead>
<tr>
<th>Registration and refreshments</th>
<th>Day one</th>
<th>Day two</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00</td>
<td>09.30-17.00</td>
<td>09.00-16.30</td>
</tr>
</tbody>
</table>

### Accommodation

When available, we have arranged a preferential rate for accommodation at the venue. To take advantage of this price, please mention that you are a Management Forum delegate.

**Email:** reservations_rembrandt@sarova.co.uk  
**Web:** www.sarova-rembrandthotel.com

For information on alternative accommodation, please visit our website: management-forum.co.uk/accommodation

### Three ways to book

- management-forum.co.uk  
- info@management-forum.co.uk  
- +44 (0)20 7749 4730

### Fees and payment

**EARLY BOOKING DISCOUNT** Book BEFORE 13 March 2020

- £1299.00 + VAT = £1558.80  
- £1819.00 + VAT = £2182.80

**FULL PRICE** Book AFTER 13 March 2020

- £1499.00 + VAT = £1798.80  
- £2099.00 + VAT = £2518.80

**Multiple booking discount for 2nd or subsequent delegates - 15%**

- £1274.15 + VAT = £1528.98  
- £1784.15 + VAT = £2140.98

### Payment options

1. Invoice which can be paid by bank transfer or credit/debit card
2. Online through our secure website when registering

### Benefits of attending:

- **Clarify** the EU regulatory requirements for signal detection
- **Learn** to use the EudraVigilance quantitative signal tool
- **Understand** the safety review cycle and the safety review meeting and process
- **Understand** EVDAS functionalities and outputs
- **Discuss** safety communication – the CCSI/DCSI and labelling
- **Gain** a better understanding of risk-benefit analysis – benefit-risk assessments and benefit-risk outcomes

**Expert trainer:**

**Graeme Ladds**  
Director, PharSafer Associates Ltd

‘Graeme is an expert on signal detection and has a lot of practical examples to animate the subject matter. Content was of high quality.’  
Antti Miikki, Santen Oy

---

**Please note:**

- FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.
- PLEASE NOTE: Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Management Forum will refund the registration fee and disclaim any further liability.

For event cancellation policy and T&Cs see our website
**Why you should attend**

Increasingly, the most common critical findings in regulatory inspections are being given for signal detection and management so the need to identify potential signals and risks in patients has never been greater. The protection of patients through robust and clear methodologies for signal detection amidst the ever-increasing regulations requires companies to have trained and competent staff to perform such activities. This course will provide a detailed overview of all aspects of safety reviews and signal detection within a company and will cover signal evaluation for both innovator and generic products under the updated Module IX signal management and quantitative assessments.

**Who should attend?**

This course will be of interest to all those working in drug safety/pharmacovigilance as well as regulatory personnel responsible for amending the labelling for products and for the production of the CCSI/DCSI.

**Previous attendees have said:**

- ‘I was really happy with this course which was complete and well presented. It gave me some valuable ideas that I could implement in our qualitative signal detection.’
  - Caroline Riaud, Ceva Santé Animale
- ‘The speaker is confident and clearly knows the subject well. The presentation is good and the speaker added lots of extra information to the content.’
  - Christopher Harper, Blue Earth Diagnostics

**Expert trainer**

**Graeme Ladds**, Director of PharSafer, has over 30 years’ experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1990 as Head of Drug Safety & Medical Information, Graeme went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. The last 17 years have been spent in his consultancy and specialist CRO company, PharSafer Associates Ltd. During this time, Graeme has been involved in providing fully outsourced global pharmacovigilance (clinical and post-marketing) as well as medical information for companies worldwide, establishing pharmacovigilance in companies, performing audits across Europe, Asia and the USA, SOP and RMP writing, safety database selections, acting as QP for companies, and helping with regulatory inspections.

**Programme**

**Day one**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00</td>
<td>Registration and refreshments</td>
<td></td>
</tr>
</tbody>
</table>
| 09.30 | An introduction to safety signals | History of safety signals  
The nature of safety signals  
The definition of safety signals  
Safety sources for signal detection |
| 10.15 | Causality and signal detection   | Causality assessments for signal review  
Data quality in safety assessments  
Causality versus incidence (DMEs and IMEs)  
Generic and innovator products |
| 11.15 | Refreshments                     |                                                                        |
| 11.30 | The safety review meeting and process | Setting up a safety review  
Risk determinations for safety review signal trackers  
Information and templates  
Logistical safety and product safety  
Information from safety reviews |
| 12.30 | Safety assessments life cycle    | Pre-clinical safety  
Clinical safety  
Class-related safety issues  
Post-marketing safety  
Product suspensions/withdrawals |
| 13.00 | Lunch                            |                                                                        |
| 14.00 | Safety assessments life cycle (continued) |                                                                        |
| 14.30 | The regulatory requirements for signal detection – Module IX | The frequency of safety reviews (risk assessment)  
The EU and US signal detection requirements  
Signal detection and benefit-risk assessments  
The regulators and signals |
| 15.00 | Refreshments                     |                                                                        |
| 15.50 | The signal review cycle          | Safety profiling  
Signal detection, validation, confirmation  
Analysis and prioritisation, assessment  
Recommendation for action |
| 17.00 | Close of day one                 |                                                                        |

**Day two**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Topics</th>
</tr>
</thead>
</table>
| 09.00 | Quantitative and qualitative signal detections | Standard MedDRA queries  
(SMQs) and signal detection  
ICSRs and case quality  
Follow-up methodology and regulatory requirements  
Events of special interest |
| 10.00 | Signals and their discussion     | Signals and DSURs  
Signals and PSURs/PBRERs  
Signals and risk management plans/REMs and minimisation  
Signals and labelling |
| 11.00 | Refreshments                     |                                                                        |
| 11.20 | Safety communication             | The CCSI/DCSI and labelling  
Triaging for safety amendments  
Emerging safety issues  
Urgent safety restrictions  
Product suspension and withdrawal |
| 12.30 | Lunch                            |                                                                        |
| 13.30 | Quantitative signal analysis     | Signal detection methodologies  
Background – why quantitative signal detection?  
Measures of disproportionality (PRR, ROR, MGPS, BCPN)  
Regulatory and industry activity (including EudraVigilance) |
| 14.30 | EVDAS and the EU                  | The PRAC and signals  
The EVDAS system  
Signals arising from EVDAS |
| 15.30 | Refreshments                     |                                                                        |
| 15.50 | Risk-benefit analysis            | Calculating the extent of benefit by indication  
Identifying significant product risks  
Benefit-risk assessments  
Benefit-risk outcomes |
| 16.30 | Close of course                  |                                                                        |

**In-house Training**

Empower your whole team with this training as an in-house programme. If you have five or more participants who could benefit from this training then we can bring our expert to you, saving you time and money.

To get a FREE consultation and to find out how we can work with you call Aleksandra, our in-house training expert, on +44 (0)20 7749 4730 or email inhouse@management-forum.co.uk

To find out more, please visit management-forum.co.uk

A certificate of attendance for professional development will be available to each participant who completes the course.