EC Medical Devices Vigilance System and Post-Marketing Surveillance

Ensuring patient safety

28-29 January 2020 London

Benefits of attending:

- **Gain** an in-depth understanding of the EU vigilance process
- **Learn** how to apply the reporting rules with real examples
- **Understand** the legal obligations for your company
- **Be aware** of the expectations from competent authorities in field safety corrective actions (FSCA)
- **Know** what a Notified Body expects from manufacturers
- **Comprehend** the importance of the risk management process
- **Hear** how various Member States handle vigilance reports
- **Clarify** the role of Notified Bodies in vigilance
- **Understand** the regulation changes affecting PMS and vigilance
- **Know** how to report adverse events during medical device studies

Co-chairs:

**Tony Sant** Group Manager, Biosciences and Implants and Adverse Incident Centre, MHRA, UK

**Dr Ekkehard Stösslein** Deputy Head of Department for Medical Devices and Head of Section for Active Medical Devices at the Federal Institute for Drugs and Medical Devices (BfArM), Germany

With a panel of key European experts including a number of competent authorities, a Notified Body and a lawyer specialising in this area

Includes: Practical and interactive exercises
EC Medical Devices Vigilance System and Post-Marketing Surveillance
28-29 January 2020, London

Why you should attend
Ensuring that a medical device remains safe and effective whilst on the market is an essential part of complying with the EU vigilance and post-marketing surveillance requirements outlined in the Directive 94/42/EC.

Competent authorities carry out market surveillance activities to certify that all devices comply with the latest regulations, ensuring that all devices in the market are safe for users. Post-marketing surveillance requires the manufacturer to monitor and review their devices to identify any need for corrective action. This activity is carried out in conjunction with authorised representatives, importers and distributors and is a key element of the manufacturer’s quality control system. It forms part of a PMS plan, which if carried out effectively can reduce the risk of adverse events. Manufacturers are then legally obliged, as part of a vigilance process, to report any serious incidents or correction measures to the relevant competent authorities.

This seminar will give you practical advice on how to comply with the EU vigilance and post-marketing surveillance requirements. It will highlight manufacturers’ legal obligations and the risks associated with litigation, as well as providing essential guidance on how to report incidents in order to remain compliant. You will also receive guidance on how to handle adverse event reporting during medical device clinical studies.

Attending these two days will offer you a unique opportunity to meet and network with competent authorities, Notified Bodies, lawyers, consultants and manufacturers to share good practice and experience.

Who should attend?
This seminar will be of importance to all those working in the medical device industry in the following roles and departments:

- Regulatory affairs managers
- Product safety managers
- Post-marketing surveillance specialists
- Global safety surveillance specialists
- Vigilance managers
- Pharmacovigilance coordinators
- Pharmacovigilance associates
- Report specialists
- Manufacturing, registration, product safety, adverse event monitoring, regulatory affairs, distribution and anyone interested in medical device vigilance in the European community

Expert faculty
Co-chairs:
Tony Sant, Group Manager, Biosciences and Implants and Adverse Incident Centre, MHRA, UK

Dr Ekkehard Stösslein, Deputy Head of Department for Medical Devices and Head of Section for Active Medical Devices at the Federal Institute for Drugs and Medical Devices (BfArM), Germany

Speakers:
Dr Grant Castle, Partner in the London office of Covington & Burling, UK
Paul Sim, Regulatory Affairs Manager, BSI Group, UK
Janette Benaddi, Independent Medical Device Consultant, UK

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Preparation
It is advisable to have read the vigilance guidelines prior to attending this event.

Group discounts are available upon request. Please contact customer services on +44 (0)20 7749 4730 or email info@management-forum.co.uk
## Programme

### Day one

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00</td>
<td>Registration and refreshments</td>
</tr>
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</table>
| 09.30 | **Welcome and introduction**  
*Dr Ekkehard Stösslein and Tony Sant*                                                   |
| 09.40 | **Introduction to post-marketing surveillance (PMS)**  
*Tony Sant*                                                                               |
| 10.20 | **In-depth review of the EU vigilance process**  
*Dr Ekkehard Stösslein*                                                                     |
| 11.00 | Discussion session                                                                            |
| 11.10 | Refreshments                                                                                 |
| 11.30 | **Application of the reporting rules**  
• Case studies  
*Group exercise led by Tony Sant and Dr Ekkehard Stösslein*                               |
| 12.20 | Discussion session                                                                            |
| 12.30 | Lunch                                                                                         |
| 13.30 | **Legal aspects of manufacturers’ reporting obligations**  
• Main EU markets and US FDA  
*Dr Grant Castle*                                                                            |
| 14.30 | **Legal aspects of FSCA**  
• Product liability issues that might arise if one fails to take appropriate corrective action  
• The powers of the regulators to act against products  
*Dr Grant Castle*                                                                            |
| 15.30 | Discussion session                                                                            |
| 15.40 | Refreshments                                                                                 |
| 16.00 | **FSCA: expectations from authorities**  
*Dr Ekkehard Stösslein*                                                                     |
| 16.30 | **Handling of FSCA: industry perspective**  
*Janette Benaddi*                                                                            |
| 17.15 | Discussion session                                                                            |
| 17.30 | Close of day one                                                                             |

### Day two

<table>
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| 09.00 | **Post-marketing surveillance: an integral part of the QA system**  
• Critical elements of risk management, CAPA, PMS, field action SOPs  
*Paul Sim*                                                                          |
| 09.30 | **Role of Notified Bodies in vigilance**  
*Paul Sim*                                                                            |
| 10.00 | **Germany and vigilance: BfArM**  
• Organisation  
• Handling of vigilance reports  
• National guidelines  
• Sharing of experiences  
*Dr Ekkehard Stösslein*                                                               |
| 10.45 | Discussion session                                                                            |
| 11.00 | Refreshments                                                                                 |
| 11.15 | **UK and vigilance: MHRA**  
• Organisation  
• Handling of vigilance reports  
• National guidelines  
• Sharing of experiences  
*Tony Sant*                                                                          |
| 12.00 | **Medical device regulation changes affecting PMS**  
*Dr Ekkehard Stösslein*                                                               |
| 12.45 | Discussion session                                                                            |
| 13.00 | Lunch                                                                                         |
| 14.00 | **Revision of vigilance guidelines**  
• Trending and FSN format  
*Tony Sant*                                                                          |
| 14.45 | Refreshments                                                                                 |
| 15.00 | **PMS and adverse event reporting during medical device studies**  
*Janette Benaddi*                                                                   |
| 16.00 | Discussion session and closing remarks                                                        |
| 16.15 | Close of seminar                                                                             |
**EC Medical Devices Vigilance System and Post-Marketing Surveillance**  
To book online go to: [management-forum.co.uk/1628](http://management-forum.co.uk/1628)

### Dates and venue

**28-29 January 2020**  
Ref: 10630

The Cavendish Hotel  
81 Jermyn Street  
London SW1 6JF  
Tel: +44 (0)20 7930 2111  
(Note: Entrance via Duke Street)

### Programme schedule

**Registration and refreshments:** 09.00  
**Day one:** 09.30 - 17.30  
**Day two:** 09.00 - 16.15

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### 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 attending the Management Forum seminar when booking your accommodation.

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[+44 (0)20 7749 4730](tel:+44%2020%207749%204730)

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### Fees and payment

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€2099.00 + VAT = €2518.80

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2. Online through our secure website when registering

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**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.

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