EC MEDICAL DEVICES VIGILANCE SYSTEM AND POST MARKETING SURVEILLANCE
27 & 28 January 2015
ADVERSE EVENT MANAGEMENT DURING MEDICAL DEVICE CLINICAL STUDIES
29 January 2015

Application to Register

27 & 28 January 2015: **EC MEDICAL DEVICE VIGILANCE & PMS -** Conf. No. N1-8115 ☐
29 January 2015: **ADVERSE EVENT MANAGEMENT DURING CLINICAL STUDIES** Conf. No. N1–8215 ☐

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

(PLEASE READ CAREFULLY)

Registration Information

N1-8115
27 & 28 January 2015
Day 1; Start 9.30 – Finish 17.30
Day 2; Start 9.00 – Finish 16.15

N1-8215
29 January 2015
Post Conference Seminar
Start 9.30 – Finish 17.00

Venue and Accommodation
The Cavendish Hotel
81 Jermyn Street, St James's,
London, SW1Y 6JF
Hotel Tel: +44 (0) 20 7930 2111
Hotel Fax:+44 (0) 20 7839 2125
Email: ***info@thecavendishlondon.com***
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate.

Directions
For directions to the hotel, please visit the link below:
http://www.thecavendish-london.co.uk/hotel-location

Conference Fees	Please Tick
N1-8115 - EC MEDICAL DEVICES VIGILANCE SYSTEM AND PMS **£1,285 + VAT if applicable**	☐
N1-8215 - ADVERSE EVENT MANAGEMENT DURING MEDICAL DEVICE CLINICAL STUDIES **£590 + VAT if applicable** **Special discounted rate available if both seminars booked together**	☐
N1-8115 & N1-8215 - Both Events **£1,675 + VAT if applicable**	☐

The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

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.
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Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact Robert Sinclair
(email: robert@management-forum.co.uk)

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14th Annual Conference on

EC MEDICAL DEVICES VIGILANCE SYSTEM AND POST MARKETING SURVEILLANCE

Ensuring Patient Safety

Benefits in 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 an Audit on PMS Systems
- **Comprehend** the Importance of the Risk Management Process
- **Hear** how Various Member States Handle Vigilance Reports
- **Meet** Key Representatives from Main Competent Authorities
- **Clarify** the Role of Notified Bodies in Vigilance
- **Keep Abreast** of the Recast of the Medical Device Directive

Chairman:
Roland Gérard, Vice President – Regulatory and Quality Affairs - International Division, St Jude Medical

With a Panel of Key European Experts from Industry, Competent Authorities, a Notified Body and a Legal Firm Specialising in this Area

27 & 28 January 2015 - The Cavendish Hotel, London

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Post-Conference Seminar

ADVERSE EVENT MANAGEMENT DURING MEDICAL DEVICE CLINICAL STUDIES

An ideal opportunity to clarify the requirements of reporting during medical device clinical studies

With:
Janette Benaddi, Director of Clinical and Consulting, NAMSA

29 January 2015, The Cavendish Hotel, London

INTRODUCTION

While the pre-market approval process has been delegated by most of the Competent Authorities to the private sector, Competent Authorities have kept the responsibility for the surveillance of their market. Because of this situation there is transfer of resource and energy to the monitoring of markets including the Vigilance System within each Member State. The evaluation of incidents notified by manufacturers and users represents a key source of information for authorities, combined with sophisticated exchange of information between EU Member States, and with other countries like USA, Japan, Canada or Australia, provides a unique insight into the performance of devices in the post production phase.

Full compliance with the Vigilance requirements laid down in Article 10 of Directive 93/42/EC is justified by the manufacturers' legal obligations, risks associated to litigation and increasing scrutiny of Member States, but mainly by the ultimate objective of providing safe devices to patients. It is essential that manufacturers ensure compliance with these requirements.

This conference provides a unique opportunity to meet Competent Authorities, Notified Bodies, Lawyers, consultants and manufacturers to understand and discuss the regulatory and legal obligations with respect to Post Marketing Surveillance including Vigilance.

WHO SHOULD ATTEND

This conference will be of importance to all those involved in the Medical Device Industry in the following departments; **Manufacturing, Research and Development, Registration, Product Safety, Adverse Event Monitoring, Regulatory Affairs, Distribution and all those interested in Medical Device Vigilance in the European Community.**

PREPARATION:

It is advisable to have read the Vigilance Guidelines prior to attending this conference.

CHAIRMAN

Roland Gérard is Vice President Regulatory and Quality Affairs International Division, St Jude Medical. He is responsible for quality and regulatory compliance including vigilance within the international product division of St. Jude Medical. His company has five major focus areas that include cardiac rhythm management, atrial fibrillation, cardiac surgery, cardiology and neuromodulation. He was a member of the Global Harmonisation Task Force Steering Committee and a member of Study Group II on Vigilance and Post Marketing Surveillance representing EUCOMED. He was President of IAPM (International Association of Prosthesis Manufacturers) and past Chairman of the IAPM Technical and Legal Committee. He is currently chairman of the EUCOMED Regulatory Affairs. Committee (RAC).

SPEAKERS

Dr Grant Castle, Partner in the London office of Covington & Burling, UK.

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

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

Paul Jenkins, Project Manager and Technical Specialist, BSi Notified Body for Medical Devices, UK

Peter Bunyitai, *Head of Department of Medical Devices, Office of Health Authorisation and Administrative Procedures, Hungary*

Satish Champaneri, Product Specialist & Certification Manager, BSi Healthcare, UK

PROGRAMME

Day One — 27 January 2015

09.30 ▶ **Chairman's Welcome and Introduction**
Roland Gérard

09.40 ▶ **Introduction to Post Marketing Surveillance**
Tony Sant

10.20 ▶ **In Depth Review of the EU Vigilance Process**
Roland Gérard

11.00 ▶ **Discussion**

11.10 ▶ **Coffee**

11.30 ▶ **Legal Aspects of Manufacturers Reporting Obligations**
- Main EU markets and US FDA

Dr Grant Castle

12.20 ▶ **Discussion**

12.30 ▶ **Lunch**

13.30 ▶ **Application of the Reporting Rules**
- Case Studies

Group Exercise led by Roland Gérard, Tony Sant and Dr Ekkehard Stösslein

14.30 ▶ **Field Safety Corrective Actions (FSCA): Expectations from Authorities**
Dr Ekkehard Stösslein

15.00 ▶ **Discussion**

15.10 ▶ **Tea**

15.30 ▶ **Legal Aspects of FSCA**
- Product liability issues that might arise if one fails to take appropriate corrective action
- The powers regulators have to act against products

Dr Grant Castle

16.30 ▶ **Handling of Field Safety Corrective Actions (FSCA) – Industry Perspective**
Roland Gérard

17.15 ▶ **Discussion**

17.30 ▶ **End of Day One**

PROGRAMME

Day Two — 28 January 2015

09.00 ▶ **Role of Notified Bodies in Vigilance**
Paul Jenkins

09.30 ▶ **How Notified Bodies Ensure Manufacturer's Compliance with the EU Vigilance System**
- Non conformities observed in auditing Post Marketing Surveillance systems

Paul Jenkins

10.00 ▶ **Post Marketing Surveillance: An Integral Part of the QA System**
- Critical Elements of Risk Management, CAPA, PMS, Field Action SOPs

Satish Champaneri *(invited)*

10.30 ▶ **Exchange of Information Between Authorities**
Dr Ekkehard Stösslein

11.00 ▶ **Discussion**

11.10 ▶ **Coffee**

11.30 ▶ **Hungary and Vigilance**
- Organisation
- Handling of vigilance reports
- National guidelines
- Sharing of experiences

Peter Bunyitai

12.15 ▶ **Germany and Vigilance: BfArM**
- Organisation
- Handling of vigilance reports
- National guidelines
- Sharing of experiences

Dr Ekkehard Stösslein

13.00 ▶ **Lunch**

14.00 ▶ **UK and Vigilance: MHRA**
- Organisation
- Handling of vigilance reports
- National guidelines
- Sharing of experiences

Tony Sant

14.45 ▶ **Electronic Reporting**
Dr Ekkehard Stösslein

15.15 ▶ **Revision of Vigilance Guidelines - Trending**
Tony Sant

16.00 ▶ **Discussion and Closing Remarks**

16.15 ▶ **Close of Conference and Tea**

POST-CONFERENCE SEMINAR

ADVERSE EVENT MANAGEMENT DURING MEDICAL DEVICE CLINICAL STUDIES

29 January 2015

With:
Janette Benaddi, Director of Clinical and Consulting, NAMSA

PROGRAMME

This seminar provides a comprehensive overview of adverse event reporting during medical device clinical trials across Europe and is suitable for those with some experience of conducting medical device studies. The seminar will include case studies of different types of adverse events, highlight the different approaches across Europe and provide practical advice on how to manage these.

▶ **The Regulatory Requirements for Monitoring and Reporting Adverse Events During Regulatory and Post Market Studies**
- Update on the changes and guidance
- MEDDEV
- ISO 14155

▶ **How to Define and Classify Adverse Events**
- Definitions
- Types of events
- Determining categories

▶ **Handling of Adverse Events During Clinical Investigations**
- Practical guidance
- What goes into the clinical investigation plan
- What Standard Operating Procedures are needed

▶ **How to Design a Data Collection Form for Recording Adverse Events**
- What goes into the form?
- Are different forms required for different studies and countries?

▶ **The Role of the Data Safety Monitoring Board**
- Who should be involved?
- How should it be constituted?
- When is one required?

▶ **The Role of the Competent Authority (CA)**
- What is the involvement of the CA
- Communicating with the CA
- What to communicate and when