MEDICAL DEVICE TRAINING DAYS

APPLICATION TO REGISTER

Please tick which course you wish to attend:

- ☐ **QUALITY MANAGEMENT SYSTEMS – N4-8110**
- ☐ **IN-VITRO DIAGNOSTICS – N4-8210**
- ☐ **ANCILLARY MEDICINAL SUBSTANCES – N4-8310**
- ☐ **OWN BRAND LABELLING, SYSTEMS AND PROCEDURE PACKS – N4-8410**
- ☐ **MANAGING MEDICAL DEVICE SOFTWARE PROJECTS – N4-8510**

Please PRINT your details:

Title..... First name.....
(Dr, Mr, Mrs, etc)

Family name .....

Position .....

Department.....

.....

Company .....

Address.....

.....

.....

City .....Post Code .....

Country .....

Tel No..... Fax No. .....

E-mail.....

Secretary's name.....

Signature .....

Substitutions may be made at any time at no extra charge

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Expiry date...../.....

☐ Cheque enclosed payable to Management Forum Limited

☐ Bank transfer on receipt of invoice

YOU MAY REGISTER BY:-

FAX +44 (0) 1483 730008

Management Forum Ltd, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK

www.management-forum.co.uk

E-mail: registrations@management-forum.co.uk

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

REGISTRATION INFORMATION

Dates **26, 27, 28, 29 & 30 April 2010**

Times **All courses** **Start 09.30 – Finish 17.00**

Registration & Coffee
All courses **09.00**

Venue
MWB Business Exchange, 33 Cavendish Square,
London W1G 0PW
Tel: +44 (0) 207 1824251

Directions
Nearest Underground station: Oxford Circus.
Map available on MF Website under Hotels and Venues.

Recommended Hotel (10-15 minute walk)
The Cavendish London, 81 Jermyn Street (main entrance in Duke Street), St James's, London SW1Y 6JF.
Hotel Tel: +44(0)20 7930 2111.
Hotel Fax: +44(0)20 7839 4369.
Email: Reservations@thecavendishlondon.com
Alternatively visit www.nearesthotels.co.uk

Registration Fee for Each Course
£440 + VAT. includes course material, lunch and refreshments.

Discounted Rates
Available on application for personnel from non-profit making organisations, academics 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 lesley@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.

If you do not want to receive future mailings from Management Forum please contact info@management-forum.co.uk
If you do not wish to receive selected third party mailings please contact info@management-forum.co.uk

Promotional opportunities will be available at this meeting.
For further information please contact Vicki Elliott
(email: vicki@management-forum.co.uk)

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

Management Forum's Medical Device Training Academy Series

MEDICAL DEVICE TRAINING DAYS

These courses have been designed to focus on specific key aspects of the medical device industry to accommodate delegates who need in depth information on a particular topic. The training will be delivered in a very interactive and flexible format, so as to accommodate delegates' specific needs.

SUPPORTED BY:

Cranfield UNIVERSITY

WILEY-BLACKWELL

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Courses:

- **Day One:** **QUALITY MANAGEMENT SYSTEMS**
- **Day Two:** **IN-VITRO DIAGNOSTICS**
- **Day Three:** **ANCILLARY MEDICINAL SUBSTANCES**
- **Day Four:** **OWN BRAND LABELLING, SYSTEMS AND PROCEDURE PACKS**
- **Day Five:** **MANAGING MEDICAL DEVICE SOFTWARE PROJECTS**

Book on one of these training days to become a member of the Medical Device Training Academy and:

- ***Receive** a £50 discount voucher on a future one or two day Management Forum Medical Device course
- **Have** an opportunity to request your training needs and input into your future CPD strategy
- ***Receive** a complimentary on-line soft skills training course
- **Make connections** via our Medical Device Training Academy blog
- ***Receive** a free OnDrugDelivery Medical Device Report
- **Get** targeted updates on future courses
- ***Receive** a 15% discount on selected Wileys publications

***This applies to new members only**

A Certificate of Attendance for Professional Development will be given for each course completed.

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

CPD CERTIFIED
The CPD Certification Service

26 – 30 April 2010
MWB Business Exchange,
33 Cavendish Square, London W1G 0PW

Day One — 26 April 2010

QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES

Course Summary

Under the European Medical Device Directives the most commonly used Conformity Assessment routes are based on the establishment, implementation and maintenance of Quality Management Systems (QMS). This tutorial will explore in detail the issues surrounding the above, including experience gained to date and changes introduced by recent amendments to the Directive and Standards.

Key Topics to Include:

- **ISO 13485:2003 and related guidance**
- **The Conformity Assessment Annexes using the QMS approach**
- **How to implement a compliant QMS**
- **Assessment of the QMS by the Notified Body**
- **Workshop on non-conformity identification, reporting and resolution**
- **Discussion will be encouraged throughout the day**

Who Should Attend:

All those who need to comply with the Directives and Quality Systems in their role within the organisation.

- Regulatory Affairs Managers
- Quality Assurance Professionals
- Product Managers
- Operations Managers
- R & D Managers

Tutor:

Will Burton, Director, RSQA

Course Information:

Date: 26 April 2010
Registration: 9.00
Start: 9.30 – Finish 17.00
Course Ref: N4-8110
Venue: MWB Business Exchange, 33 Cavendish Square, London
Price: £440 + VAT lunch and refreshments included

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

Day Two — 27 April 2010

IN-VITRO DIAGNOSTICS (IVDs)

Course Summary

This course will clarify the requirements applicable for IVDs and will highlight the important issues regarding supplier control and validation. Practical workshop exercises throughout the day will help consolidate the information provided.

Key Topics to Include:

- **Introduction to the IVD Directive**
- **What is and What is Not an IVD**
- ***Exercise***
- **Comparison with the MDD**
- **Future Changes to the IVDD**
- **Conformity with the Essential Requirements**
- **Risk Management**
- ***Exercise***
- **IVD Hot topics – Supplier control – Validation**
- ***Exercise***
- **Vigilance and Post Market Surveillance**
- ***Exercise***
- **Wrap Up**

Who Should Attend:

- Regulatory Affairs Personnel
- Quality Assurance Professionals
- Those responsible for Original Equipment Manufacturer (OEM)/Subcontractor control of IVDs

Tutor:

Sue Spencer, Head IVD, Healthcare, BSi

Course Information:

Date: 27 April 2010
Registration: 9.00
Start: 9.30 – Finish 17.00
Course Ref: N4-8210
Venue: MWB Business Exchange, 33 Cavendish Square, London
Price: £440 + VAT lunch and refreshments included

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

Day Three — 28 April 2010

ANCILLARY MEDICINAL SUBSTANCES

Course Summary

There is increasing interest in adding value to medical devices by the incorporation of Ancillary Medicinal Substances, such devices will automatically enter the highest risk classification and require a consultation with a medicines competent body. This exposes medical device companies to unfamiliar rigors of medical product regulatory requirements and pharmaceutical companies to the strange world of device regulation. This tutorial will provide guidance and advice on the regulations to consider when adding Ancillary Medicinal Substances to medical devices.

Key Topics to Include:

- **Focus on European legislation and regulation**
- **Distinction between a medical device and medicinal product**
- **The regulatory controls applied to a medical device and a medicinal product**
- **What to consider if it is a drug/device combination**
- **Sources of further information and guidance**
- **The Ancillary Medicinal Substance consultation process**
- **Common problems encountered by manufacturers during the consultation process**
- **Devices incorporating derivatives of human blood or plasma**
- **Workshop on assembling the necessary documentation for a successful consultation on a medical device incorporating an Ancillary Medicinal Substance**

Who Should Attend:

Personal from companies who have an interest in Ancillary Medicinal Substances including derivatives of human blood and plasma.

- Regulatory Affairs Managers
- Quality Assurance Professionals
- Product Managers
- Business Development Managers

Tutor:

Will Burton, Director, RSQA

Course Information:

Date: 28 April 2010
Registration: 9.00
Start: 9.30 – Finish 17.00
Course Ref: N4-8310
Venue: MWB Business Exchange, 33 Cavendish Square, London
Price: £440 + VAT lunch and refreshments included

Day Four — 29 April 2010

OWN BRAND LABELLING, SYSTEMS AND PROCEDURE PACKS

Course Summary

This course will focus on Special Conformity Assessment Routes, including 'Own Brand Labelling' and the derogation of Article 12. Practical advice will be given to ensure compliance with the requirements.

Key Topics to Include:

- **Conformity Assessment concepts and practice in general**
- **The use and assessment of 'Own Brand Labelling' (OBL)**
- **How Notified Bodies deal with 'Own Brand Labelling' applications**
- **The derogation of Article 12: 'Particular procedure for systems and procedure packs and procedure for sterilization'**
- **New Article 12a 'Reprocessing of medical devices'**
- **Refurbishing – what does this involve?**
- **Workshop on OBL**
- **Workshop on a Procedure Pack**

Who Should Attend:

Personnel from the following Departments:

- Labelling
- Quality Control
- Packaging
- Regulatory Affairs
- Marketing

Tutor:

Will Burton, Director, RSQA

Course Information:

Date: 29 April 2010
Registration: 9.00
Start: 9.30 – Finish 17.00
Course Ref: N4-8410
Venue: MWB Business Exchange, 33 Cavendish Square, London
Price: £440 + VAT lunch and refreshments included

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

Day Five — 30 April 2010

MANAGING MEDICAL DEVICE SOFTWARE PROJECTS

Is your Software a Medical Device and is it Correctly Classified?

Course Summary

The course will provide valuable assistance and advice to all MDD regulated companies reviewing the status of their product range with respect to the new directive.

Key Topics to Include:

- **The Medical Devices Directive 93/42/EEC Published as Directive 2007/47/EC - Implications for Software**
- **Overview of Software and Medical Standards**
- **Software and IEC 60601-1 ed 3**
- **Software Life Cycle Processes & IEC 62304:2006 Medical Device Software**
- **Risk Management ISO 14971 & ISO 62366 – Application of Usability Engineering to Medical Devices**
- **Developing a Technical File for a Medical Software Project**
- **Auditing a Software Project - Internal and External Auditing Techniques**
- **Q & A Session**

Who Should Attend:

Senior Management responsible for operational and quality systems ('system owners') regulatory, clinical and IT professionals working in the health care, manufacturing and medical device markets.

- QA/RA Directors, Managers and personnel
- Consultants charged with creating or evaluating software
- Software personnel programmers, developers, verification & validation engineers
- Project managers and others responsible for bringing systems online in a compliant manner
- Quality auditors responsible for auditing and evaluating medical software

Tutor:

Peter Pringle, Consultant Engineer, Intertek

Course Information:

Date: 30 April 2010
Registration: 9.00
Start: 9.30 – Finish 17.00
Course Ref: N4-8510
Venue: MWB Business Exchange, 33 Cavendish Square, London
Price: £440 + VAT lunch and refreshments included