

Informa Life Sciences' 3rd Annual

Sterilisation for Medical Devices

Practical advice from the professionals to ensure efficient sterilisation and compliance with the latest standards: from cycle design to validation

23 – 24 March 2010, Danubius Regents Park Hotel, London, UK

www.informa-ls.com/sterilisation

Your expert speaker panel includes:

The latest information
direct from notified
bodies

Stewart Brain, BSI Healthcare, UK

David Houot, LNE/G-MED Certification,
France

Majella Geraghty, NSAI, Ireland

Henry Sibun, TUV Product Services, UK

Advice and guidance
from experienced
industry figureheads

Wendie Love, Johnson & Johnson, UK

Carl Dover, DePuy International Ltd, UK

Tony Faucette, Stryker Orthopaedics,
USA

C. Philip Cogdill, Boston Scientific, USA

K. Rao Gurijala, Ph.D, Bausch and Lomb,
USA

Thierry Wagner, DuPont Medical
Packaging, Luxembourg

Caroline Murphy, Teleflex Medical,
Republic of Ireland

Judy Calt, Veryan Medical, Republic of
Ireland

Ulla Christensen, Novo Nordisk,
Denmark

Simon Redfern, Smiths Medical
International, Ireland

Sean Hanley, Boston Scientific,
Republic of Ireland

Highlights for 2010

- ✓ Essential guidance for compliance with the latest standards for **radiation**, **ethylene oxide** and **moist heat** sterilisation
- ✓ Discover the value of working well with your contract steriliser - ensure that your contractor is providing the very best service
- ✓ Gain control of your bioburden analysis and process monitoring with expert guidance
- ✓ Debate the issues surrounding sterilisation of re-usable devices: Are manufacturers providing enough information for end users? What do the regulators require?
- ✓ Explore the potential of aseptic processing and learn how to combine this with terminal sterilisation
- ✓ Review the relative merits of X-ray, E-beam and gamma sterilisation and select the most effective sterilisation technology for your product

PLUS DON'T MISS

PRE-CONFERENCE WORKSHOP

Monday 22nd March 2010

Strategies for success in the sterilisation of novel and speciality products

Led by: Wendie Love, Clinical Education Consultant, Advanced Sterilisation Products, Johnson & Johnson, UK

NEW FOR 2010

EVENING SEMINAR

Tuesday 23rd March 2010

Presenting data to auditors

Led by: Dr. Majella Geraghty, Certification and Inspections Officer, NSAI, Ireland

POST-CONFERENCE WORKSHOP

Thursday 25th March 2010

Effective process validation for sterilisation

Led by: David Houot, Certification Project Manager-Auditor, LNE/G-MED Certification, France
Abdess Naji PhD., Consultant, Auditor and Expert, Medical Devices & Health
Biotechnology, Matiere & Sante, France

informa
life sciences

To Register Please Tel: +44 (0) 20 7017 7481 Fax: +44 (0) 20 7017 7823

PRE-CONFERENCE WORKSHOP Monday 22nd March 2010

Strategies for Success in the Sterilisation of Novel and Speciality Products

09.00 Registration 09.30 Start 16.30 End of workshop
Lunch, morning and afternoon refreshments provided

This workshop will equip you with the tools to prepare an effective sterilisation strategy for new or difficult devices. Integrating a new device into your existing process cycles can be a daunting task, with many potential problem areas. Our experts will take you through the possible pitfalls, help you choose the best method for your product and help you navigate the regulatory hurdles you may encounter.

Topics to be covered

- Predict and prepare for the challenges of incorporating a new device into your existing cycle design
- Assessing your device to select the best sterilisation technology
- Dealing with ISO 14937 for “novel devices” – practical advice on how to comply with the standard

Led by:

Wendie Love, *Clinical Education Consultant, Advanced Sterilisation Products, Johnson & Johnson, UK*

Day One: Tuesday 23rd March 2010

Essential Knowledge for Compliance with ISO Standards

08:00 Registration

08:25 Chairman's welcome and opening remarks

Henry Sibun, *Audit Team Manager, TUV Product Services, UK*

08:30 An update on the tightening of sterilisation standards across the board

- Gain an understanding of the stricter interpretations of standards by the regulators
- Hear an overview of what changes are being made
- Ensure that you are in line to comply fully
- Understand the reasons for the tighter standards

Henry Sibun, *Audit Team Manager, TUV Product Services, UK*

Radiation and Gas Plasma Sterilisation

09:05 Gamma radiation: Practical advice for working with ISO 11137

- Focus on part 2 of ISO standard 11137 for radiation sterilisation
- Establishing the maximum acceptable dose and the sterilisation dose
- Learn about the changed approach to audits
- Ensure that you are in line with regulatory requirements

Carl Dover, *Vice President of Worldwide Quality Systems, DePuy International Ltd., UK*

09:40 Setting an optimum dose for gamma radiation: Overcoming the hurdles

- Overview of SAL - Sterility Assurance Level and dose setting
- The significance of product bioburden testing
- Dose setting verses dose verification
- The dose audit

Tony Faucette, *Divisional Manager, Sterilisation Sciences, Stryker Orthopaedics, USA*

10:15 Morning coffee and networking

10:45 Using X-ray and E-beam sterilisation to your advantage

- Assess how these methods compare to gamma sterilisation
- In-house, in-line, service provider: Benefits and limitations
- Examine the safety of X-ray, E-beam and gamma radiation
- Understand how to apply ISO 11137

Joern Meissner, *Managing Director, Meissner Consulting, Germany*

11:20 Practicalities of gas plasma sterilisation

- Gain a functional review of gas plasma sterilisation in practice, with real life examples
- Examine the effectiveness of this sterilisation method
- Identify compatibility issues with gas plasma
- Negotiate the regulatory aspects when dealing with gas plasma
- Gas plasma and prions: the future

Tom Lacey, *Microbiologist/Consultant, NHS Lothian, United Kingdom*

11:55 Question and answer

12:15 SPOTLIGHT SESSION

Informa Life Sciences Sterilisation for Medical Devices event brings together key figures from across the medical device community. If you would like to share your views, offer your services or demonstrate your product to leading decision-makers in this field, why not take the opportunity to host this spotlight session?

For details please contact:

Ben Edwards, Business Development Executive

Tel: +44 (20)7017 4447

Email: ben.edwards@informa.com

12:45 Lunch

Ethylene Oxide Sterilisation

14:05 Ethylene oxide sterilisation

- Ethylene oxide sterilisation: Practical application of the standard
- Gain an update on the critical requirements of ISO 11135-1:2007
- Learn about the general validation requirements
- Learn about the new emphasis on bioburden control and resistance
- Identify and justify the most difficult component of your product to sterilise

Stewart Brain, *Microbiology Team Leader, BSI Healthcare, UK*

14:40 Ethylene oxide residuals: Application of ANSI/AAMI/ISO 10993-7:2008

- Understand the key requirements of the standard
- Transition to new standard continues to late 2011, learn about the implications for your company
- Find out about the international acceptance of the harmonised standard and its implications for the industry
- Determine the procedures for accurate measurement of EO residuals

Caroline Murphy, *Sterilisation Manager, Teleflex Medical, Republic of Ireland*

15:15 Afternoon tea and refreshments

15:45 How do we avoid common pitfalls in calculation of EO residual levels?

- Explore the permitted limits for residual EO in individual devices
- Advice on how to estimate residual levels for the surface of a complex device
- Justify your calculation to regulators to avoid repeated studies
- Our experiences in identifying worst case scenarios
- Expert accounts of successful assessment of residuals

Judy Calt, *Senior Quality Engineer, Vervan Medical, Republic of Ireland*

Moist Heat Sterilisation

16:20 Moist heat: Working with ISO 17665-1

- Be updated on the critical requirements and scope of the standard
- Gain a full understanding of the implications of this standard for the sterilisation process
- Guidance on routine control of steam sterilisation processes
- Ensure you are in line with the expectations for validation

Ulla Christensen, *Project Manager, Novo Nordisk, Denmark*

16:55 Question and answer

17:15 Chairman's closing remarks and end of day one

EVENING SEMINAR Tuesday 23rd March 2010

Presenting Data to Auditors

18:15 Registration 18:30 Start 20:30 End of seminar
Dinner and refreshments will be provided

Topics to be covered

- Get a balanced perspective: Discuss your data presentation issues with an experienced regulator
- De-mystify the process of obtaining and presenting your data for auditors
- Save time and money by understanding the importance of demonstrating compliance to the current harmonised standards

Led by:

Dr. Majella Geraghty, *Certification and Inspections Officer, NSAI, Ireland*

To Register

Tel: +44 (0) 20 7017 7481

Fax: +44 (0) 20 7017 7823

Please Quote:
CQ7071

Book online: www.informa-ls.com/sterilisation

Email: registrations@informa-ls.com

Day Two: Wednesday 24th March 2010

Optimising the Efficiency of your Sterilisation Program

- 08:50** **Chairman's welcome and opening remarks**
Alan Heavey, AE (D) *Consultant and Managing Director, Sterilization Solutions Limited, UK*

Successful Monitoring of Sterilisation Cycles

- 09:00** **An examination of parametric release and biological indicators in monitoring of the sterilisation process**
- Comparison of the advantages and drawbacks of each method
 - Evaluate the best monitoring system for your sterilisation cycles and products
 - Improve your release time with parametric release
 - Achieve a reduced incubation time (RIT) for biological indicators
 - Running a successful monitoring program: What are the notified bodies looking for?
- Simon Redfern, Microbiology Manager, Smiths Medical International, Ireland**

- 09:35** **Ensuring compliance to ISO 11737-1: 2006: Microbiological test programs, validation of test methodologies and microbial characterisation**
- Be updated on the scope and the critical requirements of the standard
 - Gain an understanding of the implications of this standard on your microbiological testing and microbiological test validation program
 - Guidance on routine bioburden testing program: Things to consider on the bioburden sampling plan, sample size and sample frequency
 - What is required in microbiological characterisation: Is morphology enough?
 - Bioburden and biological indicators
- Dr. Majella Geraghty, Certification and Inspections Officer, NSAI, Ireland**

- 10:10** **Predicting what can go wrong and why in bioburden assessment**
- Expert advice on calculation of bioburden levels
 - Identify potential sources of contamination
 - Utilise best practise techniques to minimise bioburden
 - Understand the techniques for microbiological characterization
 - Deal with bioburden failures: Learn how to minimise waste
- C. Philip Cogdill, Corp. Director of Sterilisation & Microbiology, Boston Scientific, USA**

- 10:45** **Question and answer**

- 11:00** **Morning coffee and networking**

- 11:30** **Performance Qualification (PQ) of a porous load/hardware steam sterilizer – how to qualify effectively**
- Strategic planning for a successful PQ
 - The importance of the acceptance criteria in the design qualification (DQ)
 - How can I meet the current regulatory expectations?
 - Steam – the sterilisation medium; importance of testing
 - Help! – how to troubleshoot problems
- Alan Heavey, AE (D)** *Consultant and Managing Director, Sterilization Solutions Limited, UK*

Case Study Session

- 12:05** **Sterilisation for reusable devices: working effectively with ISO 17664**
- Reprocessing by the CSD: Requirements of medical devices before purchasing
 - CSD decision diagram: Can the CSD reprocess it? ISO 17664 and the manuals
 - Risk analysis
 - Designing medical devices with the experts!
- Jeroen de Geus, Quality Manager and Staff Advisor CSD, University Medical Centre Utrecht, The Netherlands**

- 12:40** **Sterilisation for reusable devices: ISO 17664 - Panel Discussion**
- Examine the challenges in providing adequate instruction for end-user sterilisation and validation, taking into account the resources available
 - Learn how to select suitable materials for re-usables: Guidance on AAMI's TIR 17
 - Gain a regulatory and hospital viewpoint of the responsibilities of manufacturers of re-usables
 - Address the critical errors made by many suppliers and improve your customer service
 - Evaluate the requirements for information to be supplied by manufactures of reusable devices, as detailed in the European Medical Device Directive
- Jeroen de Geus, Quality Manager and Staff Advisor CSD, University Medical Centre Utrecht, The Netherlands**

PANEL DISCUSSION

Robert A. Jobbins BSc, Authorising Engineer (Decontamination), Royal Sussex County Hospital, UK
Alan Heavey, AE (D) *Consultant and Managing Director, Sterilization Solutions Limited, UK*

- 13:15** **Lunch**

- 14:35** **Packaging for sterile devices: Expert guidance on ISO 11607**
- Understand what regulators require you to prove
 - Learn about the requirements for packaging materials in compliance with ISO 11607
 - Evaluate the most suitable porous packaging material to ensure sterility for your product
 - Discover the latest developments in packaging material technology: New microbial barrier testing techniques
 - Future developments of the standard
- Thierry Wagner, Regulatory Affairs Manager EMEA, DuPont Medical Packaging, Luxembourg**

- 15:10** **Expert advice on sterilisation for drug-device combination products**
- Select the best sterilisation method for your product
 - Discover how to ensure compliance with both the notified body and medical authority regulations for combination products
 - Explore ways to avoid degradation of pharmaceuticals by sterilisation techniques
 - Understand the recent change in regulations in Germany: The 93/42/EWG directive
- Anne Jury, Director, Anne Jury Associates, UK**

- 15:45** **Afternoon tea and refreshments**

- 16:15** **Introduction to aseptic processing**
- Components of aseptic processing
 - Aseptic processing as a system
 - Contamination control in aseptic processing systems - clean room design
 - Environmental monitoring
 - Validation of aseptic
 - Introduction to isolators, RABS, and conventional fill lines
- K. Rao Gurijala, Ph.D, Director of Global Quality, Center for Microbiological Excellence, Bausch and Lomb, USA**

- 16:50** **The value of working well with your contract sterilisation company: Crucial success factors**
- Fully understand your responsibilities: Who is held accountable for sterility of the final product?
 - Ensure that your contractor is utilizing the most effective sterilisation technique for your product
 - Effective contract negotiation: Strategies for minimising costs
 - Examine the Global Harmonisation Taskforce document on supplier control
 - Why was this document introduced and what does it mean for European Regulations?
- Sean Hanley, Corporate Manager, Sterilisation Department, Boston Scientific, Republic of Ireland**

- 17:25** **Question and answer**

- 17:40** **Chairman's closing remarks and end of conference**

POST-CONFERENCE WORKSHOP Thursday 25th March 2010

Effective process validation for sterilisation

09.00 Registration 09.30 Start 16.30 End of workshop
Lunch, morning and afternoon refreshments provided

Completing process validation of a sterilisation cycle is a daunting experience. In this workshop, you will obtain practical advice which will enable you to construct an effective validation plan for your products. You will leave equipped with the knowledge to ensure success in validation of the key sterilisation technologies.

Topics to be covered

- Hear step by step accounts of successful validation methods for radiation, ethylene oxide and moist heat sterilisation: Feedback on sterilisation process following audits and assessments
- Master file approach applied to radiation sterilisation: Product family and processing category
- Overcome regulatory hurdles for biological indicators: How do you show that your indicator is at least as resistant to sterilisation as the bioburden culture?
- Discover whether biological, chemical or physical verification techniques are best for your product

Led by:

David Houot, Certification Project Manager-Auditor, LNE/G-MED Certification, Notified Body n° 0459, France
Abdess Naji Ph.D., Consultant, Auditor and Expert, Medical Devices & Health Biotechnology, Matiere & Sante

To Register

Tel: +44 (0) 20 7017 7481
Fax: +44 (0) 20 7017 7823

Please Quote:
CQ7071

Book online: www.informa-ls.com/sterilisation
Email: registrations@informa-ls.com

6 Easy ways to Register

- +44(0) 20 7017 7481
 - +44 (0) 20 7017 7823
 - registrations@informa-ls.com
 - www.informa-ls.com/sterilisation
- The Bookings Department
Informa UK Ltd
P O Box 406
Byfleet
KT14 6WL

Group Bookings: To take advantage of group bookings please contact Simon Lau, Tel: +44(0) 20 7017 7165 email simon.lau@informa.com

Your VIP number is on the address label. If there is no label, please quote

Step 1: Select your workshop Pre-conference workshop W: Strategies for success in the sterilisation of novel and specialty products
 Post-conference workshop X: Effective process validation for sterilisation

Step 2: Select your pass Type of Pass	Code	Book Before 8 January 2010	Save	Book Between 8 January - 19th February 2010	Save	Book After 19 February 2010	Save
FULL PASS: Conf + pre- & post- conf w/shop + eve seminar	CQ7071CWXY	<input type="checkbox"/> £2896 + 15% VAT = £3,330.40	£400	<input type="checkbox"/> £2996 + 15% VAT = £3,445.40	£300	<input type="checkbox"/> £3096 + 15% VAT = £3560.40	£200
4 Day Pass: Conf + pre- & post- conf w/shop	CQ7071CW	<input type="checkbox"/> £2597 + 15% VAT = £2,986.55	£300	<input type="checkbox"/> £2697 + 15% VAT = £3,101.55	£200	<input type="checkbox"/> £2797 + 15% VAT = £3216.55	£100
3 Day Pass: Conf + pre/post conf w/shop + eve seminar	CQ7071CWXY	<input type="checkbox"/> £2397 + 15% VAT = £2,756.55	£200	<input type="checkbox"/> £2497 + 15% VAT = £2,871.55	£100	<input type="checkbox"/> £2597 + 15% VAT = £2986.55	
3 Day Pass: Conf + pre/post conf w/shop	CQ7071CW/X	<input type="checkbox"/> £1998 + 15% VAT = £2,297.70	£200	<input type="checkbox"/> £2098 + 15% VAT = £2,412.70	£100	<input type="checkbox"/> £2198 + 15% VAT = £2527.70	
2 Day Pass: Conf + eve seminar	CQ7071CY	<input type="checkbox"/> £1698 + 15% VAT = £1,952.70	£200	<input type="checkbox"/> £1798 + 15% VAT = £2,067.70	£100	<input type="checkbox"/> £1898 + 15% VAT = £2182.70	
2 Day Pass: Conference only	CQ7071C	<input type="checkbox"/> £1299 + 15% VAT = £1,493.85	£200	<input type="checkbox"/> £1399 + 15% VAT = £1,608.85	£100	<input type="checkbox"/> £1499 + 15% VAT = £1723.85	

Are we mailing you correctly? To update your contact details on our database please email integrity@informa.com

DELEGATE DETAILS – Please photocopy form for multiple bookings!

(Mr/Mrs/Ms/Miss/Dr) Family Name _____
Forename _____
E-mail _____
Tel _____ Fax _____
Job Title _____
Any special requirements?

To assist us with future correspondence, please supply the following details:

Head of Department: _____
E-mail _____
Tel _____ Fax _____
Booking Contact: _____
E-mail _____ Fax _____
Tel _____ Fax _____
Name of Company _____
Department _____
Address _____
_____ City _____
Postcode _____ Country _____
Tel _____ Fax _____
Nature of Company Business _____
No. of employees on your site: 1) 0-49 2) 50-249 3) 250-499 4) 500-999 5) 1000+

PAYMENT INFORMATION

Please invoice

Credit Card. Please debit my:

Card No: _____
CVV Number _____ (this is the 3 digit code on the back of your credit card)
CVV Number Amex _____ (this is the 4 digits code on the front of your credit card)
Expiry Date: _____
Signature: _____
Credit card billing address: _____

Contact Number for Card Holder: _____

Please note that cards will be debited within 7 days of your registration on to the conference

Yes I agree to the terms and conditions as stated on this form.

Delegates who do not pay with their booking are requested to provide a copy of bank transfer / credit card / cheque details to help payment allocation. Staff at the event will request a credit card guarantee for delegates without proof of payment.

Venue Details:

Danubius Hotel Regents Park
18 Lodge Road
St. John's Wood
London NW8 7JT
Tel: 020 7722 7722 Fax: 020 7483 2408
<http://www.danubiuslondon.co.uk/>

Reduced Rate Hotel Accommodation: The cost of accommodation is not included in the conference fee. Reduced rate accommodation can be booked by using the following web link: <http://www.hotelmap.com/Sterilisation> Alternatively, if you would like to book your accommodation by phone, you can call Paul Johnson, +44 20 7292 2335 quoting Special Reference Code M6JML

Conference Documentation: Cannot Attend?

For those busy executives who cannot take full advantage of this event, the papers give you a useful record of the presentations made at the event. The set of speakers papers and/or slides from the conference is available after the event for £399 + 15% VAT. Contact Customer Services on tel: +44(0) 20 7017 7481, fax: +44 (0) 20 7017 7823 or e-mail: registrations@informa-ls.com

Terms and Conditions

FEE: This includes all technical sessions, lunch and and documentation in electron format.

CANCELLATIONS: Cancellations received in writing before and on Monday 8th March 2010 will be subject to a service charge of £99. The full conference fees will remain payable after Monday 8th March 2010. Substitutions are welcome at any time. It may be necessary for reasons beyond the control of the organiser to alter the content and timing of the programme or the identity of the speakers. In the unfortunate event that an event is cancelled Informa are not liable for any costs incurred by delegates in connection with their attendance. This contract is subject to English Law.

ARE YOU REGISTERED?: You will always receive an acknowledgement of your booking. If you do not receive anything, please call us on +44(0) 20 7017 7481 to make sure we have received your booking.

DATA PROTECTION: The personal information shown on this form, and/or provided by you, will be held on a database and may be shared with other companies in the Informa Group in the UK and internationally. If you do not wish your details to be available to companies in the Informa Group please contact the Database Manager at the above address, Tel: +44 (0)20 7017 7077, Fax: +44 (0)20 7017 7828 or email: integrity@informa.com
Occasionally your details may be obtained from, or made available to, external companies who wish to communicate with you offers related to your business activities. If you do not wish to receive these offers, please tick the box

INCORRECT MAILING: If you are receiving multiple mailings or you would like us to change any details or remove your name from our database, please contact the Database Manager at the above address, Tel: +44 (0)20 7017 7077, Fax: +44 (0)20 7017 7828 or email: integrity@informa.com - quoting the reference number printed on the mailing label

ANY SPECIAL REQUIREMENTS: Please inform us if you have any special requirements by calling Customer Services on +44(0) 20 7017 7481.