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1 Day Conference

Cleanrooms and Contamination Control for Healthcare and Pharmaceuticals

26 June 2008 - Conference, 27 June 2008 - Workshop
ICO Conference Centre, London

Update on standards, regulation
and best practice

Are you clear about recent and forthcoming developments in legislation and standards for cleanrooms and contamination control?

Compliance with the relevant updated EU and UK regulations should be at the top of every cleanroom or sterile environment manager's agenda. If you work in the healthcare, pharmaceuticals or medical industries, or are tasked with managing sterile processing environments or biocontamination and infection control, you need to be aware of changes in this field.

This conference will also provide the opportunity to network and share experiences with your industry peers.

At this conference, you will:

- Be updated on standards, regulation and best practice for cleanrooms professionals
- Hear the latest information on the forthcoming changes to the BS EN ISO 14644 and BS EN ISO 14698 series and the impact of the revision of Annex 1 of the EU GMP
- Be inspired with new ideas for controlling contaminants in manufacturing cleanrooms, labs and operating theatres cost-effectively
- Gain an insight into recent industry changes, future developments and their potential impact

Cleanrooms and Contamination Control for Healthcare and Pharmaceuticals

Update on standards, regulation and best practice

Conference Programme 26 June 2008

Conference Timings

Registration: 09.00

Conference begins: 09.30

Conference closes: 17:00

Please note, timings are provided for guidance only and may be subject to change.

Chair

Gordon Farquharson

Chair BSI LBI/030, Chair CEN TC243,

Convenor ISO TC 209 WG1;

Principal Consultant – Technology Division

Bovis Lend Lease

Regulatory and Standards Information

An update on recent and forthcoming changes to regulations and legislation, and understanding and applying the BS EN ISO 14644 series of cleanrooms standards, nationally, in Europe and worldwide. Including:

- UK, EU and international regulations and how they relate to standards
- Latest advice on compliance with MHRA, EMEA, FDA and other regulations
- Updates to GMP Annex 1
- Consideration of forthcoming changes to BS EN ISO 14644 Parts 1 and 2
- Associated standards
- Developments in statistical methods for classifying data
- Air cleanliness testing and sequential sampling

Gordon Farquharson

Chair BSI LBI/030, Chair CEN TC243,

Convenor ISO TC 209 WG1;

Principal Consultant – Technology Division

Bovis Lend Lease

Annex 1 and non viable particles – practical issues for pharmaceutical cleanroom manufacturing

- Manifold and point of use particle monitoring systems and Annex 1

- Compliance with Annex 1 in grade A and B environments
- Particle counting technology
- Correlation between microbe carrying particles and particles
- The origin of the airborne particle limits in Annex 1

Tim Eaton

Sterile Manufacturing Specialist

AstraZeneca

Key Issues

Biocontamination control in cleanrooms (BS EN ISO 14698)

- General principles and methods
- Evaluation and interpretation of data
- Proposed changes – classification of airborne and surface biocontamination, risk management and cleaning techniques

Andrew Tweedie

Chairman

Scottish Society for Contamination Control

HEPA filtration test methods

- Filter leak testing in-situ to BS EN ISO 14644-3
- Introduction to PD 6609
- Manufacturers Test Standard BS EN 1822
- The issue of variation within test standards

Tim Triggs

Business Development Director

DOP Solutions

Risk management of contamination (RMC) during cleanroom manufacturing

- Introduction to Risk Management of Contamination (RMC)
- Fundamental mechanism of contamination transfer
- Sources and routes of contamination (particularly humans) and the use of risk diagrams
- Overall assessment for general cleanroom areas

- Critical area risk assessment by airborne deposition
- Risk assessment by surface contact

Tim Eaton

Sterile Manufacturing Specialist

AstraZeneca

Nanotechnology in healthcare and pharmaceuticals – contamination issues

- General considerations of nanotechnology
- Potential nano-contamination
- Relevance to healthcare and pharmaceutical facilities
- Contamination control

Dr Thomas H Treutler

Global Technology Manager

Berkshire International

Practice Update

Case study: Design and construction of hospital cleanrooms

- Isolator myths
- Hospital cleanroom standards
- Needs
- Constraints
- Awarding of contracts
- Validation
- Ancillary services

Conor Murray

Chairman

Irish Cleanrooms Society

Case study: Effective application of airborne cleanliness in orthopaedics

- Conventional ventilation vs UCV in orthopaedics
- The role of infection control in microbiological testing
- 'Theatre rituals and roles'

Joyce Bowler

Infection Control Officer

Interhealth Care Services (UK)

Post Conference Workshops

27 June 2008

Workshops run concurrently – delegates may select **either** Workshop A **or** Workshop B.

Workshop Timings

Registration: 09.30

Workshop begins: 10.00

Workshop closes: 16:00

Please note, timings are provided for guidance only and may be subject to change.

A: BS EN ISO 14644-7: working with separative devices/isolators – installation, testing and approval for hospitals

- The role of a separative device in hospitals
- Key design considerations
- Factors relating to validation of a separative device
- Rapid gassing requirements
- Leak detection in perspective
- Monitoring considerations for an isolator

Brian Midcalf

Specialist Pharmacist & Assistant PTQA Course Director
University of Leeds

B: BS ISO 21501: new standard for particle counters for cleanrooms and for testing injections and infusions

- Cleanroom classification and monitoring – the relationship between EU GMP, BS EN ISO 14644 and BS ISO 21501-4
- Particulate testing in injections and infusions – the relationship between USP<788>, EP2.9.19 and BS ISO 21501-3
- Particle counter accuracy and repeatability
- Achieving BS ISO 21501 calibration

Tony Harrison

Life Sciences Manager
Hach Ultra

Conference Speakers

Chair: Gordon Farquharson
Bovis Lend Lease

Joyce Bowler
Interhealth Care Services (UK)

Tim Eaton
AstraZeneca

Conor Murray
Irish Cleanrooms Society

Dr Thomas H Treutler
Berkshire International

Tim Triggs
DOP Solutions

Andrew Tweedie
Scottish Society for Contamination Control

Who should attend?

All those who manage or supply cleanrooms and controlled environments in the pharmaceutical and healthcare industries, NHS and hospital trusts including operating theatres, laboratories, manufacturing areas, such as:

- Quality assurance, quality control and auditing professionals
- Production managers
- Pharmacists and Qualified Persons
- Facilities managers
- Maintenance managers
- Project engineers
- Designers and consultants
- Installers
- Manufacturers and suppliers
- Cleanroom contractors
- Test and certification houses

About BSI Conferences & Training

BSI Conferences and Training offers a wide range of events ranging from topical issues such as the implications of Business Continuity to the practical implementation of a new standard.

Our conferences bring together key players to debate latest trends, regulations and issues with opportunities for delegates to take part in open discussions and debates led by panels of expert speakers. In addition, these conferences may have workshops running alongside to provide guidance and practical advice.

With relevant and up-to-date information, presented in an accessible and appropriate manner, you will leave one of our events better equipped to face your professional challenges and responsibilities.

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For further information **email** conferences@bsigroup.com
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Cleanrooms and Contamination Control for Healthcare and Pharmaceuticals

26 & 27 June 2008 - ICO Conference Centre, London

PRICING

	1 Day Conference 26 June 2008	A Post Conference 1 Day Workshop 27 June 2008	B Post Conference 1 Day Workshop 27 June 2008
Standard Rate (Non Member)	£499.00 + VAT (£586.32)	£399.00 + VAT (£468.82)	£399.00 + VAT (£468.82)
Standard Rate (Member*)	£449.50 + VAT (£527.69)	£359.10 + VAT (£421.94)	£359.10 + VAT (£421.94)
Public Sector/Charity Rate (Non Member)	£299.00 + VAT (£351.32)	£299.00 + VAT (£351.32)	£299.00 + VAT (£351.32)
Public Sector/Charity Rate (Member*)	£269.10 + VAT (£316.19)	£269.10 + VAT (£316.19)	£269.10 + VAT (£316.19)

Discounts:

* Members discount applies to members on provision of appropriate membership number or booking code on conference and/or workshop bookings.
If you have 5 or more delegates, please contact +44 (0)20 8996 7409 about group packages.

Conference Information

Full joining instructions will be sent upon receipt and confirmation of your booking. If you have not received your confirmed instructions **within 3 days**, please call Customer Services on +44 (0)20 8996 9001 to confirm your booking has been placed.

Terms and Conditions

All cancellations and transfer requests must be made in writing to the Head of Delegate Administration in Customer Services, either by email, fax or letter, contact details below. This will be acknowledged in writing.

Transfers

There is no charge for changing a delegate name providing the request is received no less than 20 working days before the start of the event.

Any request received 19-0 working days before the start of the event will be subject to a transfer charge of 20% of the fee.

Cancellation

There is no charge for cancellations received no less than 40 working days before the start of the event.

Any cancellation received 39-16 working days before the start of the event will be subject to a cancellation charge of 25% of the fee.

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Because networking with delegates from other companies add to the quality of our events, it may be necessary to cancel an event if the delegate numbers are too low. We reserve the right in our absolute discretion and without liability to cancel any event, in which case all monies will be refunded. If you are making travel or accommodation arrangements we recommend that you check the status of the event with our customer service department first. We reserve the right at any time and without prior notice to change the venue and/or speakers and/or programme from that described in the brochure. Prices are correct at time of print but may be subject to change. We accept no responsibility for the views expressed by the speakers or any other persons present at the event.


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Please state clearly the items you are booking and give your full contact details.

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If you would like to purchase a copy of the relevant standards they can now be downloaded from
www.bsigroup.com/cleanrooms