

For programme details, speakers,
and to book visit:
<http://shop.bsigroup.com/cleanroomsconference>



Early bird
bookings
Book by 6 April 2010 &
SAVE 20%!

3rd Annual Conference

Cleanrooms 2010

Regulatory compliance and energy management

9 June 2010
CBI Conference Centre, London

Do you use the BS EN ISO 14644 or BS EN ISO 14698 series of standards? Are you aware of changes that may impact on regulation? Do you need to improve the energy efficiency of your cleanroom?

Attend for:

- Updates on revisions to the BS EN ISO 14644 and BS EN ISO 14698 series of cleanroom and biocontamination standards
- Advanced information on how changes to cleanrooms standards may impact on GMP
- Best practice examples of how you can improve energy management in your cleanrooms from those that are already ahead
- An introduction to BS EN 16001 Energy management systems
- Discussion and networking opportunities with some of the leading cleanroom experts in the UK.

Book now to receive a copy of BS EN 16001 Energy management systems. Requirements with guidance for use*

Sponsors:



Media Partners:



Cleanrooms 2010

Regulatory compliance and energy management

Conference programme 9 June 2010

Chair's introduction and standards and regulation update

Changes affecting EU GMP and the FDA's CGMP – progress of revisions to the BS EN ISO 14644 and BS EN ISO 14698 series - Non-viable and viable particle cleanliness in cleanrooms

- What are the potential revisions?
- Timeline
- Impact of changes to ISO 14644 on EU GMP and the FDA's CGMP
- The need in GMP for the instrument standardization procedures and tests in ISO 21501-4
- Managing the particle counting data
- Future impact of ISO 14698 on EU GMP

Tony Harrison

UK Technical Expert,

ISO TC209 WG 01 - Non-viable Contamination

Convenor,

ISO TC209 WG 02 - Biocontamination

Technical Expert,

BSI LBI/030 - Cleanrooms

Vice Chairman,

UK Pharmaceutical Healthcare Sciences Society

Reducing emissions and improving energy management

Cleanroom HVAC and contamination control – A green challenge to the regulatory guidelines

- Principles and origins of unidirectional airflow and non-unidirectional airflow cleanrooms
- Regulatory authority cleanroom cleanliness levels recommendations and their origins
- Comparison of in operation cleanroom performance vs. regulatory authority guidelines
- Scenarios for energy savings whilst maintaining adequate contamination control
- Realistic and achievable cleanroom energy reductions

Tim Eaton

Sterile Manufacturing Specialist,

AstraZeneca

Case Study: Designing cleanrooms for more efficient energy consumption and reduced emissions

- Implications of the Carbon Reduction Commitment on operating costs
- Design consideration – Life cycle cost optimization

- Cleanroom MOT / Energy audit to identify component energy consumption and wastage
- Identifying optimal balance between regulatory compliance and energy consumption
- Satisfying the stakeholders: Production, quality, procurement and engineering
- Cleanroom re-classification (costs v benefits)
- Examples of energy efficient cleanrooms designs:
 1. New build
 2. Modifications to existing facility

Brendon McManus

Managing Director,

Clean Air Technologies

BS EN 16001 – The new European energy management standard

- What is it?
- How does it work?
- What are the benefits?
- How does it differ from ISO 14001?
- How easy is it to implement?
- Will it fit all sizes of organization?
- The practices, purpose and principles

Trevor Floyd

Principal Consultant,

TENBY Consultancy Group

BS EN 16001 – Is it appropriate for cleanrooms?

- Could BS EN 16001 be applicable to cleanrooms ?
- Potential benefits/difficulties
- Other options

Tim Triggs

Director,

DOP Solutions

Discussion Session: Cleanroom energy management solutions

- What are your needs? What issues are you facing?
- How have they been tackled?
- Advice and suggestions

Case Studies

Case study: Particulate and chemical contamination control in microelectronic and medical device manufacture

- Varied case studies into particulate and chemical contamination (SPC & SMC)
- Detection and measurement of surface product particulate and film

- The corrosive and destructive effect on product life due to outgassing material
- Compliance with new standards for SPC and SCC within the BS EN ISO 14644 standards

Dick Gibbons

Working group convenor,

BS EN ISO 14644 surface chemical contamination

UK expert,

BS EN ISO 14644 surface particle contamination group

Member,

LBI 30

Case Study: Validation of cleanroom disinfectants

- EN microbiological tests available
- Other factors to consider
- Common issues when validating disinfectants
- New techniques for the validation of disinfectant packaging

Karen Rossington

Marketing and Development Manager,

Shield Medicare

Case Study: Validating cleanrooms for pharmaceuticals manufacture

- Overall approach to cleanroom validation
- Harnessing cleanroom technology to protect product from particulate and bioburden challenge during open operations
- Importance of additional airflow visualisation (smoke) and particulate studies to support cleanroom qualification

Richard Swift

MS&T Microbiologist,

Lilly UK

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.

Drinks reception: 17:00 -

Delegates are cordially invited to a complimentary drinks reception at the close of the conference. The drinks reception is an ideal forum for networking opportunities and discussing the day's findings.

About BSI Conferences

BSI conferences bring together key players to learn about latest trends, regulations and topical 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.

www.bsigroup.com/conferences

Sponsorship and partner opportunities

Through BSI conferences and events your company will be able to reach your target market and showcase your new products and solutions. If you are interested in promoting your company, its products or services at the conference, please call **020 8996 7371** or email conferences@bsigroup.com

If you would like to work with BSI on a contra basis as either a supporting organization or a media partner for the conference, please call **020 8996 7497** or email simon.anderson@bsigroup.com

About BS EN 16001 Energy management systems. Requirements and guidance for use

BS EN 16001 will help your business establish the systems and processes necessary to improve energy efficiency. This will help to save money and reduce greenhouse gas emissions through systematic management of energy.

BS EN 16001 specifies requirements for an energy management system to enable you to develop and implement a policy and objectives which take into account legal requirements and information about significant energy aspects. It is a useful document for all types and sizes of organizations and accommodates diverse geographical, cultural and social conditions.

Read more and buy:

<http://shop.bsigroup.com/BSEN16001>

Conference outline

This conference describes how changes to the BS EN ISO 14644 cleanroom standards, and BS EN ISO 14698 biocontamination standards, are likely to impact your cleanroom operation. The event will also examine requirements for complying with GMP gives guidance on using BS EN 16001 to integrate an effective energy management system. The programme provides guidance from the UK's authority on standards and offers delegates the opportunity to benchmark processes and results against key thought leaders and operators to reduce contamination and drive the quality and efficiency of operations and processes.

Key speakers

- **Tony Harrison**, *Vice Chairman, UK Pharmaceutical Healthcare Sciences Society*
- **Tim Eaton**, *Sterile Manufacturing Specialist, AstraZeneca*
- **Richard Swift**, *MS&T Microbiologist, Lilly UK*
- **Brendon McManus**, *Managing Director, Clean Air Technologies*

Who should attend?

Industry professionals working with cleanrooms in the healthcare, pharmaceuticals and medical devices arena; including:

- Quality control managers
- Cleanroom managers
- Operations managers
- Quality assurance managers
- Compliance officers
- Facilities managers
- Maintenance managers
- Project engineers
- Engineers
- Cleanroom installers
- Cleanroom product manufacturers and suppliers



Cleanrooms 2010

Regulatory compliance and energy management

9 June 2010

FIVE EASY WAYS TO BOOK

DELEGATE DETAILS

1 Mr/Ms/Miss/Mrs/Dr/Other	First Name(s)
Surname	
Job Title	Organization
Address	
	Postcode Country
Tel	Fax
Email	
2 Mr/Ms/Miss/Mrs/Dr/Other	First Name(s)
Surname	
Job Title	Organization
Address	
	Postcode Country
Tel	Fax
Email	
BSI Membership No. (if applicable)	

PRICING

Early bird pricing Book by 6 April 2010 Please ✓ your selection(s)	Conference only* 9 June 2010
Standard rate	<input type="checkbox"/> £359.00 + VAT
SME rate†	<input type="checkbox"/> £303.00 + VAT
Public sector/charity rate	<input type="checkbox"/> £239.00 + VAT
Standard pricing Booked after 6 April 2010 Please ✓ your selection(s)	Conference only* 9 June 2010
Standard rate	<input type="checkbox"/> £449.00 + VAT
SME rate†	<input type="checkbox"/> £379.00 + VAT
Public sector/charity rate	<input type="checkbox"/> £299.00 + VAT

Discounts:

BSI members are entitled to a 10% discount. Member discount applies to members on provision of appropriate membership number or booking code on conference and/or workshop bookings
 † An SME is defined as an organization that employs fewer than 250 persons and which have an annual turnover not exceeding £45.5 million.

* Conference price includes one hard copy of BS EN 16001 Energy management systems. Requirements with guidance for use per delegate, subject to availability, to be given out on the day of the conference.

If you have 5 or more delegates, please contact +44 (0)20 8996 7745 for group package rates.

All prices are subject to VAT at the applicable UK rate.

Total Payable: £

PAYMENT DETAILS

Cheque: *Please make payable to BSI*

Credit Card: *Please complete as follows*

Credit Card details: VISA  MASTERCARD  AMERICAN EXPRESS 

Credit Card No.

Expiry Date Cardholder Name

Please debit my/our Credit Card to the sum of £

Signature Date

Your contact details will be used to complete your request. We will send you relevant information about our products and services that may be of interest to you by post or via email. If you do not wish to be kept up-to-date please tick this box. We will never supply your information to third parties for marketing purposes. BSI handles all personal information in compliance with the Data Protection Act 1998 and the EU Communications Directive 2002. Sign up now to receive FREE regular email updates from BSI on conferences and training. Register at www.bsigroup.com/newsletters

03/10

 **Online:**

<http://shop.bsigroup.com/cleanroomsconference>

 **@ Email:**

orders@bsigroup.com

 **Telephone:**

+44 (0)20 8996 9001

 **Fax:**

+44 (0)20 8996 7001

 **Mail:**

Send your completed form to:

Customer Services
BSI
389 Chiswick High Road
London
W4 4AL

Please retain a copy for your records.

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 name change requests must be made in writing to the Head of Delegate Administration either by email, fax or letter and will be acknowledged in writing.

Contact details are:
Head of Delegate Administration Customer Services
BSI

BSI Group Headquarters
389 Chiswick High Road
London W4 4AL

Fax: 020 8996 7001
Email: cservices@bsigroup.com

A full refund will be given if you cancel earlier than one calendar month before the event. If you cancel after that date or do not attend, no refund will be given. There is no charge to request a delegate name change. If you are travelling from overseas we recommend you confirm your visa (if applicable) before booking your place.

All bookings for events are subject to VAT (or local equivalent if the event is not held in the UK) and payment terms of 30 days. If you are a non UK company you may be entitled to claim back the VAT through HMRC. (see www.hmrc.gov.uk for more information).

BSI reserves the right at any time and without prior notice to change the venue and/or speakers and/or programme and/or price from that described. BSI accepts no responsibility for the views expressed by the speakers or any other persons present at the event.

BSI reserves the right to cancel the event, in which case a full refund will be given. BSI does not accept liability for any travel, accommodation or any other costs.

Delegate contact details will not be passed to any third party; however the conference handbook will include a list of delegate and company names correct at the time of print. The handbook is protected by copyright.

Attendees are not permitted to record any part of the event. All conferences will be delivered in English unless otherwise stated.



Book online at <http://shop.bsigroup.com/cleanroomsconference>