Do you operate, manage, equip, commission or build cleanrooms? Do you want to hear about the latest developments in standards and best practice to support your business?

Attend to learn about the varied issues faced by those different roles in a cleanroom’s life cycle.

This conference will give you an update on the latest developments in standards and best practice to support your business, including predicted revisions to the BS EN ISO 14644 series and the impact these will have on your operating processes and practices.

Streamed sessions and case studies enable you to select the most relevant topics to meet your learning needs.

This conference will:
- Show you how to overcome problems through operational best practice and case study examples
- Give you a briefing on successful cleanroom design - communication between cleanroom managers, commissioners, designers and builders
- Look at the sustainability factor, exploring green cleanrooms and energy saving techniques
- Give you an insight into the predicted amendments to the BS EN ISO 14644-1 and -2
- Offer an opportunity to give feedback on predicted changes to the standards.

There will also be opportunity to share experiences and network with peers during the event and drinks reception.

Post-conference workshop:
Working with separative devices and isolator technology (BS EN ISO 14644-7)
Cleanrooms and Contamination Control
Standards and Best Practice Update

Conference outline:
Cleanrooms are an essential part of operations in a variety of settings, including healthcare, pharmaceuticals, food processing, electronics and automotive. In each of these environments, it is vital that the risk of contamination and transmission is reduced to an acceptable and controllable level.

Many procurers, however, often have little idea what is required for a cleanroom, and are unable to assess the competence of the building firm contracted to construct the cleanroom. This could lead to substandard cleanrooms being built that are not fit for purpose and have to be ripped out and started again, at considerable cost. Standards exist to guide and support you in your work and prevent critical errors such as this occurring.

This conference will give you an update on the latest developments in standards and best practice to support your business, including predicted revisions to BS EN ISO 14644 series and the impact these will have on your operating processes and practices.

Who should attend?
All management involved in the commissioning, building, maintenance or operation of cleanrooms including:
- Cleanroom managers
- Operations managers
- Quality assurance managers
- Maintenance and facilities managers
- Designers and architects
- Engineers and installers
- Manufacturers
- Construction/building firms and suppliers
- Procurement managers.

Conference programme 24 June 2009

<table>
<thead>
<tr>
<th>Plenary sessions (am)</th>
<th>Plenary sessions (pm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chair’s introduction</strong></td>
<td><strong>Case study: Operational applications of Annex 1</strong></td>
</tr>
<tr>
<td>Gordon Farquharson</td>
<td>• Cleanroom particle monitoring systems to comply with Annex 1</td>
</tr>
<tr>
<td><em>Chair BSILBI/030; Chair CEN TC243 (Cleanroom technology): Convenor ISO TC 209 WG1 (Cleanrooms and associated controlled environments): Principal Consultant – Technology Division, Bovis Lend Lease</em></td>
<td>• Operational compliance with Annex 1 in Grade B areas</td>
</tr>
<tr>
<td><strong>Keynote</strong></td>
<td>• Operational compliance with Annex 1 in Grade A areas (the 5micron issue)</td>
</tr>
<tr>
<td><strong>Regulation and standards update</strong></td>
<td>• Correlation between microbe carrying particles, 0.5µm and 5µm particles</td>
</tr>
<tr>
<td>• Status of the revision of ISO 14644-1 and -2 and the other standards</td>
<td><em>Tim Eaton</em></td>
</tr>
<tr>
<td>• The April 2009 Committee Draft vote on the revision of ISO 14644-1 and -2</td>
<td>Sterile Manufacturing Specialist, AstraZeneca</td>
</tr>
<tr>
<td>• How to influence the revision to these important standards</td>
<td><strong>New trends and technologies</strong></td>
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<tr>
<td>• What will the impact be on our industries?</td>
<td>Main innovation sources for past and future Micro-Electro-Mechanical Systems (MEMS) devices</td>
</tr>
<tr>
<td>• The timeline for the potential changes</td>
<td>• Fabrication technology - eg micro-cavities for cold atom control</td>
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<tr>
<td><strong>Gordon Farquharson</strong></td>
<td>• Innovative design of micro machined structures - eg mechanical leverage system on a chip</td>
</tr>
<tr>
<td><em>Chair BSILBI/030; Chair CEN TC243 (Cleanroom technology): Convenor ISO TC 209 WG1 (Cleanrooms and associated controlled environments): Principal Consultant – Technology Division, Bovis Lend Lease</em></td>
<td>• System integration - eg multi-physical domain MEMS atom chip</td>
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<tr>
<td><strong>Energy saving in the cleanroom</strong></td>
<td>• eg integration of micro machined devices with innovative control systems</td>
</tr>
<tr>
<td>• Building management systems and energy management systems</td>
<td><strong>Key fabrication technology for future MEMS devices</strong></td>
</tr>
<tr>
<td>• Air handling units</td>
<td>• Precision wafer bonding - eg passive MEMS alignment technology</td>
</tr>
<tr>
<td>• Operations</td>
<td>• Metrology and characterization - eg actuation for optical cavity tuning</td>
</tr>
<tr>
<td>• HEPA filters</td>
<td><strong>Prof. Michael Kraft</strong></td>
</tr>
<tr>
<td><em>Tim Triggs</em></td>
<td>Nanoscale Systems Integration Group, Electronics and Computer Science, Southampton University</td>
</tr>
<tr>
<td>Director, Sales and Business Development, DOP Solutions</td>
<td><strong>Cleanroom testing and certification requirements</strong></td>
</tr>
<tr>
<td><strong>Cleanroom testing and certification requirements</strong></td>
<td>• Innovative design of MEMS devices - eg actuation for optical cavity tuning</td>
</tr>
<tr>
<td>• Airflow measurements</td>
<td><strong>Prof. Michael Kraft</strong></td>
</tr>
<tr>
<td>• Filter leak testing</td>
<td>Nanoscale Systems Integration Group, Electronics and Computer Science, Southampton University</td>
</tr>
<tr>
<td>• Recovery time testing</td>
<td><strong>Discussion session</strong></td>
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<tr>
<td>• Airflow visualization</td>
<td>Put your questions to the experts</td>
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<tr>
<td>• Formal classification</td>
<td>See opposite page for streamed sessions</td>
</tr>
<tr>
<td><strong>Gordon Farquharson</strong></td>
<td><strong>Drinks reception</strong></td>
</tr>
<tr>
<td><em>Chair BSILBI/030; Chair CEN TC243 (Cleanroom technology): Convenor ISO TC 209 WG1 (Cleanrooms and associated controlled environments): Principal Consultant – Technology Division, Bovis Lend Lease</em></td>
<td>17:00 - Delegates are cordially invited to attend a drinks reception at the close of the conference.</td>
</tr>
</tbody>
</table>

**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 attend a drinks reception at the close of the conference.
A1. Maintenance of controlled environments
- Control of bacterial spores
  - Transfer disinfection
- Comparison of different active ingredients
- What level of microbial efficacy is required?
  - BS EN test methods
- Factors to consider when choosing a disinfectant

Karen Rossington
Marketing and Development Manager
Shield Medicare Ltd - a Division of Ecolab

B1. Particle technology – measuring/monitoring systems
- Particle counter technology - how they work and the assumptions they make
- Particle counters - types of instruments
- Particle counter application - classification vs. monitoring vs. problem diagnosis
- Particle counters and monitoring systems

Tim Russell
Field Market Developer
TSI Inc

C1. Potent compounds – Health & Safety vs. cleanroom operation
- Risks to workers or risks to customers?
- Just how risky is it?
- Systematic exposure risk management
- Design tensions between safety and cleanroom requirements
- How do I know it’s safe?

Justin Mason
Managing Director
SafeBridge Europe

D1. Risk management of cross contamination
- How should hazardous substances be characterized?
- Can they be safely manufactured on a multipurpose plant?
- Cross contamination - hazard vs. risk - a source of confusion
- Current regulation - too specific or too vague?

Malcolm Holmes,
Contributing author, Risk-MaPP, International Society for Pharmaceutical Engineering (ISPE)

A2. Case study: Design of cleanrooms using BS EN ISO 14644-4 and its application to modular cleanrooms
- New challenges to cleanroom design and where modular cleanrooms fit
- Impact of changes to ISO 14644-1 and -2 on ISO 14644-4
- Getting the User Requirements Specification (URS) right, normative vs. informative information
- Modular vs. traditional comparison
- Designing for flexibility

Conor Murray
Managing Director
3dimension Limited

B2. Cleanrooms and controlled zones: isolators, Restricted Access Barrier Systems (RABS) and transfer devices
- The separation concept – isolating the contamination source of people from clean or aseptic processes
- Barrier separation choices – isolators and RABS; introducing the new PHSS RABS Monograph
- Impact of barrier selection on cleanroom design

James Drinkwater
Process Director
Bioquell (UK) Ltd;
Vice Chairman
Pharmaceutical and Healthcare Sciences Society (PHSS)

C2. Providing solutions for HEPA filter, cleanrooms and safety cabinet testing
- HEPA filter system testing
- Standards and BS/EN/ISO methods
- Trends
- Practical solutions
- Reporting of results

Tim Triggs
Director
Sales and Business Development, DOP Solutions

D2. Chemical contamination control
- Problems caused by surface and airborne chemicals
- Control of out-gassing materials in construction and operation
- New ISO standards for classification of air and surface chemicals

Dick Gibbons
Contamination Control Chairman
Society of Environmental Engineers (SEE)
Post-conference workshop 25 June 2009

Working with separative devices and isolator technology (BS EN ISO 14644-7)

• The role of separative devices in cleanrooms (or controlled zones)
• Key design considerations
• Factors relating to the validation of separative devices
• Controlling the microbial level of the separative device; use of gas sanitization
• Leak detection in perspective
• Optimal ways of monitoring the separative device

Brian Midcalf
Assistant PTQA Course Director
University of Leeds

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.

About the BS EN ISO 14644 series

The BS EN ISO 14644 series of standards is intended to cover all relevant aspects of contamination and bio-contamination control technology for cleanrooms.

There are currently 8 published standards in this series, providing definitions, quality determinations, recommendations for contamination control and basic criteria for the design, construction, start-up and operation of cleanrooms.

For more information, visit www.bsigroup.com/14644series

Interested in construction?

Attend BSI’s 2nd annual conference on life cycle costing in September. Register at www.bsigroup.com/lifecyclecosting

About BSI workshops

BSI’s conference workshops provide detailed learning, guidance and practical advice through small groups and one-to-one interaction with highly skilled and knowledgeable tutors. The workshops can provide a greater depth of understanding and enable you to get to grips with challenging and technical subjects.

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
**Pricing**

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<th><strong>EARLY BIRD PRICING</strong></th>
<th>Conference only</th>
<th>Conference and workshop package</th>
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<tr>
<td><strong>Early Bird Pricing</strong></td>
<td>24 June 2009</td>
<td>24-25 June 2009</td>
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<td><strong>Standard rate</strong></td>
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<tr>
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<th><strong>PRICING (AFTER 20 MAY 2009)</strong></th>
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<tr>
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<tr>
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<td>£494.10 + VAT (£568.22)</td>
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*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.

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DELEGATE DETAILS

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Surname  
Job Title  
Organization  
Address  
Postcode Country  
Tel Fax  
Email  
BSI Membership No. (if applicable)

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

PRICING

Bookings received on or before 20 May 2009 will be booked at the early bird rates. Bookings received after 20 May 2009 will have normal rates applied.

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<tr>
<th>Booking selection</th>
<th>Conference only 24 June 2009</th>
<th>Conference and workshop package 24-25 June 2009</th>
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<tr>
<td>Standard rate Non member</td>
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<td>Standard rate Member*</td>
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<td>SME rate** Non member</td>
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<td>SME rate** Member*</td>
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<td>Public sector/charity rate Member*</td>
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Discounts:  
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** An SME is defined as an organization that employs fewer than 250 persons and which have an annual turnover not exceeding £45.5 million. If you have 5 or more delegates, please contact +44 (0)20 8996 7409 about group packages. Please note streams 1 and 2 run concurrently. Delegates may change streams between presentations. Please indicate your session and stream selections when booking e.g. A1, B2, C1 and D2. Please indicate which session you would like to attend below:

Stream 1  
A1  B1  C1  D1

Stream 2  
A2  B2  C2  D2

Total Payable: £

PAYMENT DETAILS

Cheque: Please make payable to BSI

Credit Card: Please complete as follows

Credit Card details:  
Credit Card No.  
Expiry Date  
Cardholder Name

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

Signature  
Date

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05/09