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cleanroom construction

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## ISO Cleanroom Standards &amp; Their Impact on your Operations



On the 5th October 2016, the ISPE is organising a special one-day workshop on the ISO Cleanroom Standards aimed at helping you to understand and implement the newly revised cleanroom standards ISO 14644 part 1 and part 2. Expert in the industry Gordon Farquharson discusses the changes below:

It's hard to believe that it took 10 years to revise well established cleanroom standards first published in 1999. Eventually, in December 2015 we saw the publication of BS EN ISO 14644-1&2:2015. The UK provided the convenorship for this important revision, and also contributed experts to a multinational team involved in the revision process.

It is important to understand that all British, European, and International standards require periodic review and revision. Every five years or so, ISO requests that the relevant technical community consider and vote on whether a standard should be revised or be approved for a further five-year period. Back in 2004/5 this process triggered a rigorous review and update process which manifest itself in the publication of the two revised standards related to the fundamental matter of cleanroom cleanliness classification by airborne particles, and performance monitoring.

The changes will affect every cleanroom on the planet, and will require changes to the cleanroom classification procedure. Now, the good news is that the fundamental cleanliness levels, ISO 1-9 don't change, it is aspects of the testing to determine compliance with class limits that has changed. Two main elements of change are the number of sampling locations required for classification is generally increased, and the statistical foundation for evaluating the class from the data is changed.

ISPE is providing a one-day focused education event on 5 October 2016 to explore the background to these changes, highlight some of the challenges, reflect on the GMP impact, and through practical example work through and illustrate the classification procedure.

I'll look forward to meeting you at the workshop.

Speaker Gordon Farquharson - Working in International Standardisation

For more information and to register visit the ISPE website

# 2016 ISPE UK Affiliate Annual Conference, Table Top Exhibition and Awards Dinner

In Partnership with the GAMP® COP UK Forum  
and 25<sup>th</sup> Anniversary Celebrations

This year's Conference will focus on:

## Technologies for the 21<sup>st</sup> Century

**Thursday 10 November 2016**  
**Queen's Hotel, Leeds, LS1 1PJ**

08:00 Registration, Coffee, Exhibition and Networking

08:55 Welcome and Introduction

09:00 Developing a Global Technology Strategy for  
AstraZeneca

*Mark Proctor, AstraZeneca*

09:30 Facilities of the Future

*Richard Alldread, CPI Biologics*

10:00 Trends and Applications in Aseptic Filling  
Technology - the Future Is Here!

*Paul Valerio, IPS - Integrated  
Project Services*

10:30 Refreshments & Exhibition

11:00 The rapidly growing pipeline of Antibody Drug  
Conjugates (ADCs) - problems that need solving  
and the ever increasing demand for manufacturing  
capacity

*David Simpson, Glythera*

11:30 Overcoming Commercialisation Challenges for Cell  
and Gene Therapy

*Stephen Ward, Catapult Cell and  
Gene Therapy*

12:00 Technologies for the 21<sup>st</sup> Century - MHRA's role

*Ian Rees, MHRA*

12:30 Lunch & Exhibition

14:00 Showcase Session

Single Use Fermenters & Large Volume ImPulse  
Single Use Mixer

*Anthony Richards, Thermo Fisher  
Scientific*

Membrane emulsification; an enabling technology  
for the 21<sup>st</sup> Century

*Richard Holdich, Micropore  
Technologies Ltd*

Continuous on line bioburden monitoring for pharmaceutical waters

*TBC, Mettler Toledo*

Assessing the particulate containment performance of pharmaceutical equipment – sampling and analytical considerations

*Owen Butler,  
Health and Safety Lab*

dbDNA: Rapid, in vitro, scalable and cost-effective DNA amplification

*Jill Makin,  
Touchlight Genetics*

The value offered by single use, integrated continuous bioprocessing and how to get started

*Rob Noel, Pall*

15:30 Refreshments & Exhibition

16:00 Data Handling – Big Data

*Dirk Vogel, GE Healthcare*

16:30 Sustainability Supply Chain School – ‘How the school can help you!’

*Lucy Hind, Covance Laboratories*

17:00 **Close**

### Annual Conference Prices:

18:30 Drinks Reception

ISPE Members: £140 inc VAT

19:15 ISPE UK Annual Awards Ceremony

ChemE Members: £160 inc VAT

19:45 Dinner

Pharmig Members: £160 inc VAT

Student Rate: £75 inc VAT

21:30 After Dinner Speaker – John Moloney

ISPE Non-members: £240 inc VAT

### Annual Awards Dinner Prices:

Table of 10: £930 inc VAT  
Individual Dinner Ticket: £95 inc VAT

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For more information contact: Robyn Stewart, CFS Events Ltd  
Tel: +44 (0)1438 751519 Email: [robyn@cfsevents.co.uk](mailto:robyn@cfsevents.co.uk)



## Notes from the Summer Conference

June saw the first UK Affiliate Summer Conference, covering the latest developments of the ISPE Baseline Guides and Good Practice Guides (GPGs), as well as providing current regulatory advice. Around 50 delegates from many of the pharmaceutical and biopharmaceutical industry disciplines attended the conference and gained an understanding of the most recent updates to the Guides and an insight into new and upcoming guidance documentation; including the Sustainability Handbook, the revised Oral Solid Dose (OSD) Baseline Guide, and Operational Excellence and Single Use technologies GPGs.

The event, organised this year by Southern Region, provided an excellent opportunity for networking during refreshment breaks, as well as, during the sessions, ample time for open discussion and debate both during or at the end of each talk as well as through the inclusion of a panel of the contributors at the end of the sessions.

The event was held at the National Motorcycle Museum in Birmingham. This proved to provide an excellent central location for delegates, a

comfortable venue and an opportunity to see some classic British motorbikes.

The UK Affiliate will be developing the programme for next year's Summer Conference, with the rotating organisational benefit of support from, this time, the North West Region, identifying the hot topics for industry selected from the ISPE Guidance Documents Committee (GDC)'s 2017 publications matrix. We hope you will be able to join us, to make the 2017 event even more of a success.

“As a speaker at conferences in Europe and the US it was refreshing, to be with a group of like-minded professionals that enjoy open, spirited discussion, engagement and amiable banter – and then have a chance afterwards to nip downstairs and see some of the best of inspirational British engineering”



Rob Bowen - ISPE Central Chair



ardmac

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