



Establishing & Demonstrating Control in GMP Cleanrooms

This continues our ongoing 'back to basics' theme, this time with a focus on the changes proposed in Annex 1 and their impact on QRM, setting requirements for cleanroom design, classification and Viable and Non Viable EM.

Panel Session on proposed Annex 1 Changes

Speakers include John Hargreaves, ASPEC giving a French perspective

Location:
Radisson Blu Hotel
Little Island, Co Cork

Tuesday Nov 20th 2018
09:00 – 14:00

Why attend?

This Back to Basics seminar is your opportunity to invest yourself in critical aspects of GMP Cleanrooms.

GMP Expert Panel - Impact of Annex 1 proposed changes on GMP Cleanrooms

- Standards referred to
- QRM and Risk Assessments
- Contamination control principles
- Viable EM, inc role of IMD
- Non Viable EM
- PALs and MALs

Who should attend?

This Back to Basics seminar will be of benefit to:

- Key personnel involved in Engineering and Facilities
- Key personnel involved in C&Q and Quality
- Supply Chain companies who provide facilities and services to the Life Science industry, including:
 - Designers & Specifiers
 - Contractors
 - Testing and Certification
 - EM
 - Gowning & Consumables

The Irish Cleanroom Society presents its 2018 Back to Basics series - **Establishing & Demonstrating Control in GMP Cleanrooms - Annex 1 Impact**

The first session will focus on standards and proposed Annex 1 changes. This will be followed by a panel session on GMP cleanroom aspects of the Annex 1 issued for public comment earlier in 2018. **Conor Murray, Convenor of the NSAI Irish Cleanroom Standards Mirror Group will chair an expert panel, made up of the speakers plus invited experts, debating the underlying technical challenges/implications.**

Conor Murray – 3dimension Cleanrooms, Chairman ICS & Head of Delegation at TC 209

Conor is Chairman of the Irish Cleanroom Society and Convenor of working group, WG-5 of CEN TC 243 on Biocontamination Control. Conor is Head of Delegation for Ireland at ISO TC 209 and Irish SME on working groups, WG04 on Cleanroom Design and WG13 on Cleanroom Energy Management. Conor was the Irish SME on the revision of ISO 14644-1 & -2:2015. Conor is Convenor of the Irish Cleanroom Standards Mirror Group for NSAI. Conor is an engineer by profession and an independent technical expert in Cleanrooms and Biosafety Labs.



Guest Speaker – John Hargreaves, ASPEC Microbiologist – A French GMP Perspective

John Hargreaves has been engaged with users and regulatory authorities from the early 90s, including the evolution of EU GMP Annex 1 to the present reassessment. In 2008 John designed an ASPEC training course for inspectors on the use of EN ISO 14644 standards for GMP Inspectors. This was in liaison with EMA, PIC/S and AFSSAPS, the French agency. John is an author of peer reviewed articles and guidelines, he also teaches in two pharma faculties.



Attendance Details

• BOOK ONLINE at www.cleanrooms-ireland.ie/events

Bookings will be accepted on a first come first served basis.

• The fee for the full day event is:
**€50 for ICS members
and €100 for non
members.**

• The fee includes copies of all presentations, a certificate of attendance, refreshments and soup & sandwiches.

• A number of Vendor tabletops will be there in support of the event

• The seminar will be held at the **Cork Radisson Blu Hotel** in Little Island, Cork

For directions please visit:

<https://www.radissonhotels.com/en-us/hotels/radisson-blu-cork-spa/contact>

SEMINAR PROGRAMME

Irish Cleanroom Society Back to Basics Annual Seminar – **20th November 2018**,
Radisson Blu Hotel, Little Island, Co. Cork

08:00	Registration & Coffee/Tea
09:00	Introduction – Conor Murray, Chairman Irish Cleanroom Society
09:05	‘Back to Basics – HVAC design air modelling and new HEPA filter technology’ Speakers: Sean O’Reilly – Global Director Strategic Initiatives and Chris Hews – High Purity Segment Manager UK & Ireland, AAF/Daikin Sean and Chris will talk about advances in CAD HVAC design modelling from a clean air filtration perspective and new HEPA filter technology.
09:45	‘Back to Basics - Application of ISO 14644-1 & -2 and pr17141 principles to Annex 1’ Speaker: Conor Murray, Convenor, Irish Cleanroom Standards Mirror Group, NSAI Conor will give an update on the application of ISO14644-1 & -2:2015, with the emphasis on Non Viable monitoring, as well as progress on the revision and update of EN 14698, now called prEN17141 as part of Viable EM, all in relation to Annex 1, in terms of the proposed changes.
10:30	‘Back to Basics - Cleanroom Standards & EM Issues – a French Perspective’ Speaker: John Hargreaves. Consultant, ASPEC (French Cleanroom Society) John will give a French perspective on the proposed changes to Annex 1 and its impact on cleanroom design and EM, Non Viable and Viable.
11.15	Short Break
11:30	EXPERT PANEL SESSION ‘Addressing Cleanroom challenges arising from the proposed changes to Annex 1, as part of the public consultation process.’ Panel: Speakers plus invited experts Moderator: Conor Murray, Irish Cleanroom Standards Mirror Group, NSAI A number of cleanroom related submissions were made by various working groups in ISO TC209 to the EMA during the public consultation period in the first half of 2018. .All the responses from all the organisations are currently being reviewed by the EMA & PIC/s task group. We will focus on a number of specific areas, inc PALs & MALs, segregation, Isolator applications and challenges.
13.30	Wrap Up and Close (followed by Soup and Sandwiches)

Enquiries to Seminar Organisers: Chris Delaney and Conor Murray;
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