



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 Cleanroom operations.

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, WG01 on Airborne Contamination, WG04 on Cleanroom Design and WG13 on Cleanroom Energy Management. 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.



