



Back to Basics - 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

ICS 'Back to Basics' Seminar Programme – Annex 1 Changes

- 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'**
Speaker: 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 perspective and new HEPA filter technology.
- 09:45** **'Back to Basics – Application of ISO 14644-1 & -2 and pr17141 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 the application of Non Viable monitoring, as well progress on the revision and update of EN ISO 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, member of 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 organizations 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)**