Irish Cleanroom Society

ISO 14644 -1&-2:2015 Notes on Workshop Seminar

ISO 14644-1 & -2 are the cornerstone and bedrock of Cleanroom Standards. The original -1 standard has been around since 1999 and -2 since 2000. WG 01 has been in a systematic review process for nearly 9 years to create a better and more practical and useable standard. So now we need to help people update their QMS, Commissioning & Qualification/Performance Verification documents for classification and periodic repeat classification. Most of the attendees are coming from GMP Life Sciences so there will be an emphasis on GMP applications.
This is a workshop seminar, in 2 parts so the focus is less on teaching and more on guiding attendees in how to apply the new standards.

Morning Technical session 09:00 - 12:00

The morning is a technical session where we will go through the detail of the 2 standards - Existing vs New, background to the changes, the history and issues and challenges that were addressed. The emphasis will be on ISO 14644-1:2015 as this is for Classification. We will discuss ISO 14644-2:2015 but more in the context of the conditions around periodic repeat classification and give the principles of designing a non viable monitoring programme based on a risk assessment. There are numerous examples in the Annexes and we will use these to show simple and straightforward ways to apply and use the standards.
We will discuss the important changes to ISO 14644-2:2015 and the relationship to the new ISO DIS 14644-3 in terms of removal of the original Table 1 covering annual HEPA filter Leak Testing, Airflow Volumes and Room Differential Pressures.
Everyone will get a copy of the 2 new standards (hard copy or electronic depending on their choice), after they book and pay but BEFORE the 25th February so they have time to prepare.

Afternoon Workshop session 12:00 - 17:00

This will include a working lunch. The objective and purpose of the workshop is to help attendees update their Cleanroom Classification Testing Protocols, SOPs, etc or be able to review updated SOPs for their Cleanroom by others. We want to give coaching face to face time with the experts to small groups or in some cases more than one from the same company during the afternoon. This is where the attendees can raise their particular project or cleanroom and we can coach them on the changes required to comply with the new standards.

The details need to be worked out but each expert will have a particular emphasis and expertise. Conor comes from a Cleanroom Design perspective so will be looking at the oversight of updated Test Packs/Test Protocols as well as the design of Non Viable EM programmes to comply with -2. Lene is a User so she has already been reviewing and updating her Cleanroom QMS and approving 3rd party Test Protocols for Classification AND Non Viable EM programmes arising from -2. Andre has been an Instructor and Examiner in the CTCB-I training courses. He is a member of WG 03 on Metrology so his practical experience in testing cleanrooms as part of his day job will be particularly relevant as he has had to update his own company's test protocols.