



Annex 1 – A Call to Action!

The new Annex 1 is finally out! - Impact on GMP Cleanrooms

This is the 3rd in our **Annex 1 Roadshow** series, coming to 7 industry locations around the country (Cork, Dublin, Limerick, Belfast, Athlone, Galway and Sligo), continuing our 'back to basics' theme, on the new Annex 1 guidance (a EMA & PIC/s joint effort). We will focus on QRM and a formal CCS (Contamination Control Strategy), setting requirements for cleanroom design, Classification vs Monitoring, and Total Particles & Viable EM. The first roadshows in Cork at the Radisson Blu hotel in Little Island, on the 12th December 2022 and near Dublin on the 31st January 2023 created great discussion among attendees. While there is never enough time during these workshops to get into every nuance and subtlety of some key clauses, it is clear the Life Science industry has its work cut out to meet the deadline in August 2023.

This is a Free to Attend event, with refreshments provided
Prior Registration and terms apply, supported by our sponsors

Morning - Annex 1 Introduction & Panel Discussion

A series of short bullet point presentations will target key elements and clauses of the new Annex 1 including QRM and CCS, relationship to Pharma 4.0, links to ISO 14644 standards, context with other Annexes (Annex 11 - Data Integrity & Annex 15 - Q&V), as well as other GMP guidance (ATMPs & short shelf-life products).

Afternoon – Workshops on Key Clauses

This will be a series of round table sessions where attendees can discuss and debate specific issues and challenges around key clauses in the new Annex 1 (now 59 pages vs 16), before sharing outcomes and conclusions with everyone.

Clauses to be covered include how to deal with the 5 Micron particle size at Cleanroom Classification, the link to Environmental Monitoring, Qualification during Simulated Operations, Air velocity at Working Position, Airflow Viz, role of PALs, MALs & PTHs for segregation, Isolator applications and challenges in continuous EM, including adoption of ARMM.

Location:

South Court Hotel, Raheen, Limerick

Thursday, 2nd March 2023

09:30 – 16:30



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- 09:00** Registration & Refreshments
- 09:15** Introduction – Conor Murray, Chair TC5, Healthcare Standards, NSAI
- 09:30** Short Vendor Presentations - Annex 1 from a product and services perspective (up to 3 x 10 Minutes, inc. Videos) Vendors – TBA, refer to www.cleanrooms-ireland.ie
- 10:00** **The new Annex 1 - Scope, Principles & Rationale**
Speaker: Conor Murray, Convenor, Irish Cleanroom Standards Mirror Group, NSAI
3 x 15-minute short bullet point presentations on background and context.
- 10:45** Short Break
- 11:00** Short Vendor Presentations - Annex 1 from a product and services perspective (up to 3 x 10 Minutes, inc. Videos) Vendors – TBA, refer to www.cleanrooms-ireland.ie
- 11:30** **Panel Discussion – Key Clauses, Implications & Challenges**
Conor Murray, Convenor WG2 ISO/TC 209 Microbiological Contamination Control,
[Joe Brady \(subject to availability\), Life Science Consultant, Risk Management & ATMP](#)
- 12.30** Break for Lunch
- 13:30** Short Vendor Presentations - Annex 1 from a product and services perspective (3 x 10 Minutes, inc. Videos) Vendors – TBA, refer to www.cleanrooms-ireland.ie
- 14:00** **AFTERNOON WORKSHOP SESSION (Examples below, but Attendees decide)**
- What does a CCS look like, where does it reside and what size is it?
 - 5 Micron particle size at Cleanroom Classification, and link to Monitoring
 - Qualification during Simulated Operations
 - Air velocity and Airflow Viz at Working Position, reconciliation vs ISO 14664-3
 - Role of PALs, MALs & PTHs for segregation, as per ISO 14644-4
 - Isolator applications and challenges in EM, including adoption of ARMM
- 16:30** Wrap Up and Close