PDA Microbiology in CCS Workshop 2026

Agenda

Thursday, 14 May

SGT Standard Time (UTC +8:00)

09:30 – 10:15	**Effectiveness of the Sampling Procedures** This presentation explores how key microbiological factors influence the reliability of contact plate sampling within the context of the updated EU GMP Annex 1 and modern Contamination Control Strategies (CCS). Through practical testing, the study evaluated the impact of sampling pressure, duration, surface type, dehydration, air sampling method, and streaking technique on microbial recovery. Results showed the impact of variations in pressure and contact time, as well surface type, plate dehydration, and disinfectant residues influence on microbial recovery. Comparison between direct plating and practical assays results are compared in aim to provide reliable tool and justification for validation purposes due to greater environmental stress. The presentation provides actionable insights to optimize sampling consistency, support validation, and reinforce contamination monitoring best practices within pharmaceutical cleanrooms. This topic has been developed based on pharmaceuticals environmental monitoring teams request across Europe, and has been presented at several occasions over the last months during seminars and conferences across Europe (Sweden, Denmark, Poland, France, and South America (Brasil). **Marc Mauro** , International Sales Manager, *Pharma Media Dr. Müller*
10:15 – 11:00	**Facility Air Flow Visualization and Microbial Monitoring in CCS/CCPs – Challenges and Future USP Remedy** Airflow visualization plays a critical role in contamination control strategies, informing the understanding and management of airborne microbial risk. However, variability in how these studies are designed, executed, and interpreted often undermines their value and contributes to compliance challenges. This presentation will connect regulatory expectations, microbiological risk, and real-world inspection outcomes to highlight where airflow visualization succeeds—and where it frequently fails. Practical recommendations will be shared to strengthen airflow visualization studies as an integrated component of contamination control plans. The session will also explore emerging USP standards discussions that aim to change the visualization paradigm in sterility assurance. **Edward C. Tidswell PhD**, Executive Director QA, *Merck & Co., Inc.*
11:00 – 11:45	**Microbial Qualification** **David Keen** , Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*
11:45 – 12:45	**Lunch Break**
12:45 – 13:30	**Challenges in Cleanroom Installations and Maintenance** **Andy Hopkins** , Senior Director, *Lachman Consultants*
13:30 – 14:15	**Water/Cleanroom Contaminations** **Miriam Guest** , Senior Principal Scientific Advisor, *Charles River Laboratories*
14:15 – 15:00	**Session 6** **Erika A. Pfeiler PhD**, Senior Consultant - Microbiology, *ValSource, Inc.*
15:00 – 15:30	**Coffee Break**

15:30 – 16:45	**Mock Audit Exercises: Evaluating CCS Readiness** **Michie (Mei Kuen) Ong** , Executive Director, Head of Product Quality, *Gilead Sciences*