

PDA From Findings to Fixes: Strengthening CCS in Aseptic Manufacturing Workshop 2025

Agenda

Thursday, 6 November

South Korea Standard Time Standard Time (UTC +9:00)

09:30 – 10:30	CCS as A Path to Productivity: Cleanroom Requalification Christian Scheuermann , Global Technical Services Manager, <i>Charles River Laboratories</i>
10:30 – 11:00	Coffee Break
11:00 – 12:00	Root Cause Analysis of CCS Failures: Tools and Techniques David Keen MRSB CBiol , Director Pharmaceutical Microbiology & Consulting, <i>Ecolab Life Sciences</i>
12:00 – 13:30	Lunch Break Tracking and Trending Tool Demonstration: Charles River's Microbial Identification Services and Trend Analysis Solution Jeonghun Shin's presentation aligns with Charles River's Contamination Control Strategy by introducing microbial identification services that support proactive contamination management. He highlights how the T&T Tool enables traceable environmental monitoring through data tracking and trend analysis. Using 21 CFR Part 11-compliant tools, the system ensures secure handling of microbial data, including frequency and distribution of identified organisms—providing actionable insights for risk assessment and contamination control. • Jeonghun Shin , Account Manager II, <i>Charles River Laboratories</i>
13:30 – 14:30	Corrective and Preventive Actions (CAPA) Linked to CCS Gaps Steven Bowen Ph.D. , Principal Consultant, <i>Eliquent Life Sciences</i>
14:30 – 15:00	Break
15:00 – 16:15	Mock Audit Exercises: Evaluating CCS Readiness Michie (Mei Kuen) Ong , Executive Director, Head of Product Quality, <i>Gilead Sciences</i>