



Agenda

PDA Microbiology in CCS: Challenges & Opportunities Workshop 2025

Thursday, 8 May

08:30 – 09:30

Registration

09:30 – 10:30

Key Points For a Pre-approval Inspection: Taking Into Consideration Current Regulatory Landscape

Andy Hopkins, Senior Director, *Lachman Consultants*

10:30 – 11:00

Coffee Break

11:00 – 12:00

Incorporating Bioburden & Biofilm Management As Part of A Holistic CCS Program

Related Technical Reports (TR): Technical Report No.69: Bioburden and Biofilm Management in Pharmaceutical Operations

David Keen, MRSB CBiol, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

12:00 – 13:15

Lunch Break

13:15 – 14:15

Best in Class Holistic Contamination Control Strategy

Related Technical Reports (TR): Technical Report No.90: Contamination Control Strategy Development

Miriam Guest, Senior Principal Scientific Advisor, *Charles River Labs, Microbial Solutions*

14:15 – 15:30

The H₂O₂ Bio-decontamination validation lifecycle: A practical approach to achieve a validated and fully understood process

Workshop will be conducted during this session.

Kate Marshall, Technical Director, *Protak Scientific*