

# PDA CCS: Controlling Personnel and Material Risks in Cleanrooms Workshop 2025

## Agenda

**Wednesday, 15 October**

AEDT Daylight Time (UTC +11:00)

08:30 – 09:00 **Registration**

### Session 1

**Welcome to the workshop and overview of Contamination Control Strategy (CCS) expectations**

09:00 – 09:15 • **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*

**Challenges faced by industry - Warning letters and a US perspective**

09:15 – 09:35 • **James N. Polarine MA**, Principal Consultant, *STERIS*

**Challenges faced by industry - an Annex 1 author and ex-MHRA inspectors perspective**

09:35 – 09:55 • **Tracy Moore**, CEO, *TM Pharma Group*

**PDA/ANSI (Standard 03-2025): Standard Practice for Quality Risk Management of Aseptic Processes - another tool for your QRM toolbox**

09:55 – 10:15 • **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*

**Q&A Discussion**

• **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*

• **James N. Polarine MA**, Principal Consultant, *STERIS*

10:15 – 10:30 • **Tracy Moore**, CEO, *TM Pharma Group*

• **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*

10:30 – 11:00 **Coffee Break**

### Session 2

11:00 – 11:10 **Overview of personnel contamination risks and case study scenario for the workshop exercise**

**Workshop Exercise - Contamination Control Strategies for personnel in cleanrooms and facilities**

• **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*

• **James N. Polarine MA**, Principal Consultant, *STERIS*

11:05 – 11:35 • **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*

• **Tracy Moore**, CEO, *TM Pharma Group*

- **Richard Chai** , Senior Technical Service Manager, *STERIS Corporation*

11:35 – 11:55 **Discussion on personnel workshop exercise outcomes**

11:55 – 12:15 **Presentation on personnel risks and control strategies**

12:15 – 13:00 **Lunch Break**

### Session 3

13:00 – 13:10 **Overview of material and equipment contamination risks and case study scenario for the workshop exercise**

**Workshop Exercise - Contamination Control Strategies for material and equipment transfer in cleanrooms and facilities**

- **James N. Polarine MA**, Principal Consultant, *STERIS*
- **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*
- **Tracy Moore** , CEO, *TM Pharma Group*
- **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*
- **Richard Chai** , Senior Technical Service Manager, *STERIS Corporation*

13:40 – 14:00 **Discussion on material and equipment workshop exercise outcomes**

14:00 – 14:35 **Presentation on material and equipment risks and control strategies**

14:35 – 15:05 **Coffee Break**

### Session 4

15:05 – 15:15 **Overview of Cleaning and Disinfection as a Contamination Control Strategy and case study scenario for the workshop exercise**

**Workshop Exercise - Cleaning and Disinfection Contamination Control Strategies**

- **James N. Polarine MA**, Principal Consultant, *STERIS*
- **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*
- **Tracy Moore** , CEO, *TM Pharma Group*
- **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*
- **Richard Chai** , Senior Technical Service Manager, *STERIS Corporation*

15:45 – 16:00 **Discussion on cleaning and disinfection workshop exercise outcomes**

16:00 – 16:30 **Case Study**

16:30 – 16:40 **Final Q&A Discussion**

16:40 – 16:45 **Closing Remarks**