

# 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

This seminar will cover recent regulatory and guidance updates on cleaning and disinfection and contamination control in cleanrooms. Current FDA Warning Letters and 483's will be discussed related to cleaning and disinfection, materials transfer, and contamination control. Recent updates from the new Annex I, PDA's Technical Report #70 as well as USP General Chapter <1072> will all be reviewed with an interactive exchange with attendees.

- **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

This session will provide an overview of the key concepts from the recent PDA/ANSI standard 03-2025, "Quality Risk Management for Aseptic Processing." The standard provides an approach to conduct a risk assessment to inform the contamination control strategy (CCS), including (but not exclusive to) that for product produced by aseptic processing.

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

#### Q&A Discussion

10:15 – 10:30

- **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*
- **James N. Polarine MA**, Principal Consultant, *STERIS*
- **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

Evaluating and controlling potential contamination risks posed by personnel and their movements throughout cleanrooms and facilities.

11:00 – 11:10

#### Overview of personnel contamination risks and case study scenario for the workshop exercise

11:00 – 12:20	<b>Workshop Exercise - Contamination Control Strategies for personnel in cleanrooms and facilities</b>	
	11:05 – 11:35	<ul style="list-style-type: none"> <li>• <b>Lisa Bennett MSc</b>, Director, <i>LB Consulting Australia Pty Ltd</i></li> <li>• <b>James N. Polarine MA</b>, Principal Consultant, <i>STERIS</i></li> <li>• <b>Kelly Waldron PhD</b>, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i></li> <li>• <b>Tracy Moore</b> , CEO, <i>TM Pharma Group</i></li> <li>• <b>Richard Chai</b> , Senior Technical Service Manager, <i>STERIS Corporation</i></li> </ul>
		11:35 – 11:55 <b>Discussion on personnel workshop exercise outcomes</b>
		11:55 – 12:15 <b>Presentation on personnel risks and control strategies</b>
12:15 – 13:00	<b>Lunch Break</b>	
13:00 – 14:35	<b>Session 3</b> Assessing and controlling contamination risks posed by materials and equipment as they move from the warehouse to the most critical zone (Grade A).	
	13:00 – 13:10	<b>Overview of material and equipment contamination risks and case study scenario for the workshop exercise</b>
	13:10 – 13:40	<b>Workshop Exercise - Contamination Control Strategies for material and equipment transfer in cleanrooms and facilities</b> <ul style="list-style-type: none"> <li>• <b>James N. Polarine MA</b>, Principal Consultant, <i>STERIS</i></li> <li>• <b>Kelly Waldron PhD</b>, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i></li> <li>• <b>Tracy Moore</b> , CEO, <i>TM Pharma Group</i></li> <li>• <b>Lisa Bennett MSc</b>, Director, <i>LB Consulting Australia Pty Ltd</i></li> <li>• <b>Richard Chai</b> , Senior Technical Service Manager, <i>STERIS Corporation</i></li> </ul>
		13:40 – 14:00 <b>Discussion on material and equipment workshop exercise outcomes</b>
		14:00 – 14:35 <b>Presentation on material and equipment risks and control strategies</b>
14:35 – 15:05	<b>Coffee Break</b>	
15:05 – 16:45	<b>Session 4</b> Cleaning and Disinfection, an essential element of any Contamination Control Strategy.	
	15:05 – 15:15	<b>Overview of Cleaning and Disinfection as a Contamination Control Strategy and case study scenario for the workshop exercise</b>
	15:15 – 15:45	<b>Workshop Exercise - Cleaning and Disinfection Contamination Control Strategies</b> <ul style="list-style-type: none"> <li>• <b>James N. Polarine MA</b>, Principal Consultant, <i>STERIS</i></li> <li>• <b>Kelly Waldron PhD</b>, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i></li> <li>• <b>Tracy Moore</b> , CEO, <i>TM Pharma Group</i></li> <li>• <b>Lisa Bennett MSc</b>, Director, <i>LB Consulting Australia Pty Ltd</i></li> <li>• <b>Richard Chai</b> , Senior Technical Service Manager, <i>STERIS Corporation</i></li> </ul>
		15:45 – 16:00 <b>Discussion on cleaning and disinfection workshop exercise outcomes</b>

	16:00 – 16:30	<b>Case Study</b>
	16:30 – 16:40	<b>Final Q&amp;A Discussion</b>
16:40 – 16:45	<b>Closing Remarks</b>	