

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
09:00 – 10:30	Session 1
	Welcome to the workshop and overview of Contamination Control Strategy (CCS) expectations 09:00 – 09:15 <ul style="list-style-type: none">• Lisa Bennett MSc, Director, <i>LB Consulting Australia Pty Ltd</i>
	Challenges faced by industry - Warning letters and a US perspective 09:15 – 09:35 <ul style="list-style-type: none">• James N. Polarine MA, Principal Consultant, <i>STERIS</i>
	Challenges faced by industry - an Annex 1 author and ex-MHRA inspectors perspective 09:35 – 09:55 <ul style="list-style-type: none">• Tracy Moore , CEO, <i>TM Pharma Group</i>
	PDA/ANSI (Standard 03-2025): Standard Practice for Quality Risk Management of Aseptic Processes - another tool for your QRM toolbox 09:55 – 10:15 <ul style="list-style-type: none">• Kelly Waldron PhD, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i>
	Q&A Discussion 10:15 – 10:30 <ul style="list-style-type: none">• Lisa Bennett MSc, Director, <i>LB Consulting Australia Pty Ltd</i>• James N. Polarine MA, Principal Consultant, <i>STERIS</i>• Tracy Moore , CEO, <i>TM Pharma Group</i>• Kelly Waldron PhD, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i>
10:30 – 11:00	Coffee Break
11:00 – 12:20	Session 2
	Overview of personnel contamination risks and case study scenario for the workshop exercise 11:00 – 11:10
	Workshop Exercise - Contamination Control Strategies for personnel in cleanrooms and facilities 11:05 – 11:35 <ul style="list-style-type: none">• Lisa Bennett MSc, Director, <i>LB Consulting Australia Pty Ltd</i>• James N. Polarine MA, Principal Consultant, <i>STERIS</i>• Kelly Waldron PhD, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i>• Tracy Moore , CEO, <i>TM Pharma Group</i>

		<ul style="list-style-type: none"> • Richard Chai , Senior Technical Service Manager, <i>STERIS Corporation</i>
	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	
13:00 – 14:35	Session 3	
	13:00 – 13:10	Overview of material and equipment contamination risks and case study scenario for the workshop exercise
	13:10 – 13:40	Workshop Exercise - Contamination Control Strategies for material and equipment transfer in cleanrooms and facilities <ul style="list-style-type: none"> • James N. Polarine MA, Principal Consultant, <i>STERIS</i> • Kelly Waldron PhD, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i> • Tracy Moore , CEO, <i>TM Pharma Group</i> • Lisa Bennett MSc, Director, <i>LB Consulting Australia Pty Ltd</i> • Richard Chai , Senior Technical Service Manager, <i>STERIS Corporation</i>
	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	
15:05 – 16:45	Session 4	
	15:05 – 15:15	Overview of Cleaning and Disinfection as a Contamination Control Strategy and case study scenario for the workshop exercise
	15:15 – 15:45	Workshop Exercise - Cleaning and Disinfection Contamination Control Strategies <ul style="list-style-type: none"> • James N. Polarine MA, Principal Consultant, <i>STERIS</i> • Kelly Waldron PhD, Business Unit Manager, Quality and Manufacturing Science Consulting, <i>ValSource, Inc.</i> • Tracy Moore , CEO, <i>TM Pharma Group</i> • Lisa Bennett MSc, Director, <i>LB Consulting Australia Pty Ltd</i> • Richard Chai , Senior Technical Service Manager, <i>STERIS Corporation</i>
	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	