PDA Aseptic Manufacturing Excellence Conference 2025

Agenda

Monday, 13 October

AEDT Daylight Time (UTC +11:00)

08:00 – 08:45	**Registration**	
08:45 – 10:30	**Opening Plenary – Advancing Excellence in Aseptic Manufacture**	
	08:45 – 08:55	**Welcome & Opening Remarks** • **Justine D. Mann MBA, BSc**, Chief Executive Officer, CBE Pure Solutions, *President, PDA Australia Chapter*
	08:55 – 09:25	**Adoption of PIC/S PE009-17** • **Matt Davis** , Director, Inspections Section - Manufacturing Quality Branch, *Therapeutic Goods Administration*
	09:25 – 09:55	**'Designing the State of Control' within the Contamination Control Strategy (CCS)** • **Tracy Moore** , CEO, *TM Pharma Group*
	09:55 – 10:30	**Panel Discussion and Q&A**
10:30 – 11:10	**Coffee Break**	
11:10 – 12:35	**Session 1- Innovative Tools & Processes to Assure Sterility and Quality**	
	11:10 – 11:15	**Welcome Remarks** • **Mylinh La PhD**, Senior Laboratory Manager, *CSIRO*
	11:15 – 11:40	**Risk Based Approach for Design of Environmental Monitoring Programmes** • **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*
	11:40 – 12:05	**Rapid Micro - Real-world challenges – and solutions – for the use of biofluorescent particle counters in Grade A aseptic filling applications** • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva*
	12:05 – 12:20	**Q&A**
12:20 – 12:35	**Product Demo by CAI**	
	12:20 – 12:35	**Bridging the Gap from Project Mode to Sustained Operations** • **Lewis O'Brien** , Country Manager-Australia & New Zealand, *CAI*
12:35 – 13:35	**Lunch Break**	

Session 2- Sustaining & Maintaining Quality in Aseptic Manufacture

13:35 – 15:10	13:35 – 13:40	**Welcome Remarks** • **Micheal Schafferius** , Application Specialist for Filtration and Quality, *Sartorius Stedim Biotech Australia*
	13:40 – 14:05	**Developing a CCS (Contamination Control Strategy) for ATMP Cleanrooms** • **James N. Polarine MA**, Principal Consultant, *STERIS*
	14:05 – 14:30	**Sterility Assurance – Recent PDA publications to guide alignment with PIC/S Annex 1 Implementation** • **Bruce Loxley** , Science Advisory Board member 2022-2028, *PDA*
	14:30 – 14:55	**Navigating Quality and Compliance in a Biologics CDMO** • **Melissa El Khouri** , Head of Quality, *BioCina Adelaide*
	14:55 – 15:10	**Q&A**
15:10 – 15:50	**Coffee Break**	

Session 3 - Concurrent A: Case Studies in Quality and Compliance Across Aseptic Manufacturing

15:50 – 17:10	15:50 – 15:55	**Welcome Remarks** • **Nadia Seidel** , Site Operational Excellence Lead, *Pfizer*
	15:55 – 16:20	**Challenges and Opportunities in Radiopharmaceutical Manufacturing** • **Robert Raposio Ph.D., MMgt**, Process Performance Manager, *ANSTO Nuclear Medicine*
	16:20 – 16:35	**Case Study - Operational Readiness- A Practical Approach** • **Christopher Cassidy** , Operational Readiness Director, *Pfizer*
	16:35 – 16:50	**Case Study - Risk Based Qualification of Facilities in Practice** • **Samuel O'Callaghan** , Managing Director - Australia & New Zealand, *PSC Biotech*
	16:50 – 17:05	**Q&A**
	17:05 – 17:10	**Closing Remarks**

Session 3 - Concurrent B: GMP Compliance and Quality Assurance in Veterinary Sterile Products

15:50 – 17:25	15:50 – 15:55	**Welcome Remarks** • **Justine D. Mann MBA, BSc**, Chief Executive Officer, CBE Pure Solutions, *President, PDA Australia Chapter*
	15:55 – 16:20	**GMP Changes** • **Malcom Hammond** , Director, Manufacturing Quality and Licensing & Assurance, *Australian Pesticides and Veterinary Medicines Authority (APVMA)*
	16:20 – 16:45	**Aseptic Manufacture & the APVMA Code: Meeting Today's Standards, Shaping Tomorrow's Compliance** • **Louise White** , APVMA Auditor, Director and Consultant, *SeerPharma Pty Ltd*

	16:45 – 17:10	**QRM Basics** • **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*
	17:10 – 17:25	**Q&A**
	17:25 – 17:30	**Closing Remarks** • **Justine D. Mann MBA, BSc**, Chief Executive Officer, CBE Pure Solutions, *President, PDA Australia Chapter*
17:10 – 19:10	**Networking Reception**	

Tuesday, 14 October

AEDT Daylight Time (UTC +11:00)

07:30 – 08:45	**Registration**	
07:45 – 08:45	**Breakfast Session (Part 1)**	
	07:45 – 08:45	**How to Use Lifecycle Risk Assessments to Improve Quality and Operational Processes** • **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*
08:45 – 09:00	**Break**	
09:00 – 09:15	**Breakfast Session (Part 2)**	
	09:00 – 09:15	**Welcome to Day 2 - updates from the PDA Australia Chapter and Global PDA Network** • **Justine D. Mann MBA, BSc**, Chief Executive Officer, CBE Pure Solutions, *President, PDA Australia Chapter* • **Sadman Bhuiyan** , Project Manager, Scientist and Educator, *INOVIQ Ltd.*
09:15 – 10:25	**Session 4- Sterile Container Innovations: Meeting Annex 1 Expectations with Confidence**	
	09:15 – 09:20	**Welcome Remarks** • **Sadman Bhuiyan** , Project Manager, Scientist and Educator, *INOVIQ Ltd.*
	09:20 – 09:45	**Implementation of Annex 1 by Primary Packaging Suppliers: A Case Study for Improved Compliance via Advanced Particle Control and Reduced Interventions** • **Colleen O'Brien MS**, Strategy and Technical Affairs, *Gerresheimer*
	09:45 – 10:10	**A Practical Road Map for Compliance to the Container Closure Requirements in the EU GMP Annex 1** • **Derek I. Duncan PhD**, Director Product Lines, *LIGHTHOUSE Instruments*
	10:10 – 10:25	**Panel Discussion and Q&A**
10:25 – 11:00	**Coffee Break**	
	Session 5- Maintaining a State of Control: Strategies for Robust Aseptic Processing	
		Welcome Remarks

11:00 – 12:35	11:00 – 11:05	• **Jo Sherriff** , Engineering Compliance Manager, *SeerPharma Pty. Ltd.*
	11:05 – 11:30	**Cleaning Classified Rooms to meet EU Annex 1 requirements** • **James N. Polarine MA**, Principal Consultant, *STERIS*
	11:30 – 11:55	**GMP Myth Busting** • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva*
	11:55 – 12:20	**Aseptic Processing – Emerging expectations or a paradigm shift?** • **Bruce Loxley** , Science Advisory Board member 2022-2028, *PDA*
	12:20 – 12:35	**Panel Discussion and Q&A**
12:35 – 13:35	**Lunch Break**	
13:35 – 14:50	**Session 6- QC Innovation Spotlight: Case Studies in Advanced Testing for Sterility Assurance**	
	13:35 – 13:40	**Welcome Remarks** • **Craig Stephens** , Global Head of Quality Control Operations, *CSL*
	13:40 – 13:55	**Case Study - Optimisation of Mycoplasma Testing using BioFire** • **Melissa Damino** , Director of Quality Control, Tullamarine, *CSL Seqirus*
	13:55 – 14:10	**Case Study - rFC Endotoxin Testing** • **Robyn Hofer** , Operations Manager, *CBE Pure Solutions*
	14:10 – 14:25	**Case Study - Implementation of Automated EM Plate Reader** • **Mark Gracie** , LTS Manager, *Pfizer*
	14:25 – 14:50	**Q&A**
14:50 – 15:30	**Coffee Break**	
15:30 – 17:10	**Closing Plenary - Annex 1 Hot Topics: Paradigm Shifts and GMPs for the 21st Century**	
	15:30 – 15:35	**Welcome Remarks** • **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*
	15:35 – 16:00	**PUPSIT - risk considerations and compliance** • **Matt Davis** , Director, Inspections Section - Manufacturing Quality Branch, *Therapeutic Goods Administration*
	16:00 – 16:10	**Introduction to the Panel Discussion** • **Lisa Bennett MSc**, Director, *LB Consulting Australia Pty Ltd*
		Expert Panel Discussion and Q&A • **Tracy Moore** , CEO, *TM Pharma Group* • **Matt Davis** , Director, Inspections Section - Manufacturing Quality Branch, *Therapeutic Goods Administration*

	16:10 – 17:00	• **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva* • **James N. Polarine MA**, Principal Consultant, *STERIS* • **Malcom Hammond** , Director, Manufacturing Quality and Licensing & Assurance, *Australian Pesticides and Veterinary Medicines Authority (APVMA)*
17:00 – 17:10	**Closing Remarks** **Justine D. Mann MBA, BSc**, Chief Executive Officer, CBE Pure Solutions, *President, PDA Australia Chapter*	