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** This presentation outlines the TGA's adoption of PIC/S GMP version 17, effective 1 September 2025. It covers the consultation process, key stakeholder feedback, and agreed implementation strategies. Emphasis is placed on Annex 1 changes, including contamination control and CCS requirements. The session highlights major differences from version 16, industry concerns, and the TGA's phased approach to compliance, ensuring alignment with international GMP standards and improved sterility assurance. • **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)** This session examines how to achieve and maintain a state of control in aseptic manufacturing by integrating design, controls, and monitoring within a contamination control strategy (CCS). Drawing on Annex 1 expectations and recent regulatory findings, it highlights common failures and their consequences. Attendees will learn how sound design prevents contamination, effective controls sustain compliance, and monitoring verifies performance—ensuring product quality and patient safety are not compromised. • **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** This session will review the use of the Hazard Analysis and Critical Control Points (HACCP) QRM tool to support the design of environmental monitoring (EM) programs. The approach integrates key concepts from ICH Q9(R1), ISO 14644, and EU Annex 1 to evaluate the risk of controlled environments to deliver sampling locations and frequency for both routine EM and EMPQ. • **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** While biofluorescent particle counting (BFPC) technology has been around for a number of years, in relative terms it is very new compared to the decades-old methods of monitoring an environment for microbial contamination with growth media. Join this session to learn more about the advantages that real-time microbial detection offers over traditional agar-based methods and, more importantly, what it takes to adopt it for Grade A monitoring. • **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** Operational Readiness is often the missing link between capital project execution and operational performance. CAI's approach embeds readiness into project delivery to reduce risk, accelerate timelines, and avoid late-stage surprises. Developed over decades of experience, we'll show how applying a structured readiness framework across people, quality, systems, and facility workstreams can improve delivery outcomes, reduce dependence on "heroic" startup efforts, and ensure teams are fully prepared for Day One performance. The result: enhanced project delivery that's operationally sustainable and regulator-ready. • **Lewis O'Brien** , Country Manager-Australia & New Zealand, *CAI*
12:35 – 13:35	**Lunch Break**	
13:35 – 15:10	**Session 2- Sustaining & Maintaining Quality in Aseptic Manufacture**	
	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** This seminar will cover a contamination control strategy approach to materials transfer of critical items into barrier systems, cleanrooms, air locks, RABS, and Isolators. Critical discussion points how to decontaminate process parts which cannot be cleaned and sterilised out of place. There will be a focus on how to control hard to proactively prevent contamination from viruses, spores (fungal and bacterial) and vegetative bacteria. Recent case studies from ATMP cleanroom facilities will be discussed and how to control bioburden from entering aseptic areas. will be discussed in relation to incubators and pass thru decon. Published data will also be covered to convey effective methods in control bioburden into ATMP cleanrooms and BSCs. This presentation well be a holistic approach to controlling bioburden from entering cleanrooms and BSCs. • **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** Related Points to Consider (PtC): Points to Consider for Restricted Access Barrier Systems - Annex 1 Implementation • **Bruce Loxley** , Science Advisory Board member 2022-2028, *PDA*
	14:30 – 14:55	**Navigating Quality and Compliance in a Biologics CDMO** This presentation covers navigating quality and compliance responsibilities and processes as a biologics CDMO in the microbial, plasmid, and mRNA manufacturing modalities. It will focus on key principles related to phase appropriate manufacturing with a focus on PDA TR 56, industry best practice, and alignment between client and CDMO responsibilities. • **Melissa El Khouri** , Head of Quality, *BioCina Adelaide*

	14:55 – 15:10	**Q&A**
15:10 – 15:50	**Coffee Break**	
15:50 – 17:10	**Session 3 - Concurrent A: Case Studies in Quality and Compliance Across Aseptic Manufacturing**	
	15:50 – 15:55	**Welcome Remarks** • **Nadia Seidel** , Site Operational Excellence Lead, *Pfizer*
	15:55 – 16:20	**Challenges and Opportunities in Radiopharmaceutical Manufacturing** Radiopharmaceuticals play a pivotal role in modern nuclear medicine, offering precise diagnostic imaging and targeted therapeutic solutions. This presentation explores the production and application of two key isotopes manufactured at the Australian Nuclear Science and Technology Organisation (ANSTO): Technetium-99m (Tc-99m) and Lutetium-177 (Lu-177). Tc-99m, the most widely used diagnostic isotope globally, is produced via the decay of Molybdenum-99 and is essential for imaging a wide range of physiological functions. Lu-177, a beta-emitting therapeutic isotope, is increasingly used in targeted radionuclide therapy for cancers such as neuroendocrine tumours and metastatic prostate cancer. The talk will provide an overview of the challenges and opportunities manufacturing processes involved in isotope production at ANSTO. • **Robert Raposio Ph.D., MMgt**, Process Performance Manager, *ANSTO Nuclear Medicine*
	16:20 – 16:35	**Case Study - Operational Readiness- A Practical Approach** Integrating operational capital projects from engineering to commercial phases can be challenging, especially in aseptic manufacturing where balancing quality, cost, and supply is crucial. This case study highlights improvements made at Pfizer Melbourne to enhance project delivery, prepare for change, and maximize start-up capacity through new technologies, integrated workflows, and strategic workforce planning. • **Christopher Cassidy** , Operational Readiness Director, *Pfizer*
	16:35 – 16:50	**Case Study - Risk Based Qualification of Facilities in Practice** Risk-based Commissioning and Qualification streamlines the traditional qualification process by focusing testing and documentation efforts on systems and functions that directly impact product quality, patient safety and data integrity. This case study encapsulates risk-based facility qualification in practice at an aseptic fill-finish biologics manufacturing site, highlighting key learnings, benefits and opportunities to improve efficiency, quality alignment and overall project clarity. • **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 – 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** The APVMA is currently drafting a revised Australian code of Good Manufacturing Practice (GMP) for veterinary chemical products (Code of GMP). This presentation will discuss why the APVMA is revising the Code of GMP, progression to date of the revision, what are the major changes that may affect aseptic manufacturing and the current timeline for these changes. • **Malcom Hammond** , Director, Manufacturing Quality and Licensing & Assurance, *Australian Pesticides and Veterinary Medicines Authority (APVMA)*
		Aseptic Manufacture & the APVMA Code: Meeting Today's Standards, Shaping Tomorrow's Compliance

15:50 – 17:25	16:20 – 16:45	Sterile manufacturing demands the highest level of control, where even the smallest lapse can compromise product safety. In Australia, the Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates sterile products through its Code of Good Manufacturing Practice (GMP), which was published in 2007 based on the first version of the PIC/S Guide to GMP. A revised Code is expected to be published soon, bringing the framework closer to contemporary international standards and raising the compliance bar for sterile veterinary manufacturers. This session will provide a focused overview of APVMA GMP compliance, covering the regulatory framework, inspection approach, and sterile-specific expectations, including cleanroom classification, environmental monitoring, aseptic process simulations, sterilisation validation, and data integrity. Common inspection findings—such as gaps in environmental monitoring, media fill design, and cleaning validation—will be discussed, along with practical strategies for compliance and inspection readiness. • **Louise White** , APVMA Auditor, Director and Consultant, *SeerPharma Pty Ltd*
	16:45 – 17:10	**QRM Basics** This session will review key concepts of Quality Risk Management from ICH Q9 (R1) and provide recommendations on what every company, large or small, should do to ensure their QRM program is successful at identifying and controlling risk to product quality and patient safety. • **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** This interactive session will describe lifecycle or “living” risk assessments, how to create them, and their benefits, and will provide a mental model to help attendees envision the tangible value offered by these types of assessments. Attendees will then work together to determine how these risk assessments can be used to improve quality and operational processes, including topics such as deviation and complaint investigations, change control, process improvement, and knowledge management. • **Kelly Waldron PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*
08:45 – 09:00	**Break**	
	Breakfast Session (Part 2)	
		Welcome to Day 2 - updates from the PDA Australia Chapter and Global PDA Network This presentation will provide a strategic overview of recent activities, initiatives, and collaborative efforts led by the PDA Australia Chapter, the Student and Early Career Professional (SECP) subdivision, and the broader global PDA network. Attendees will gain insights into the Chapter’s evolving role in advancing pharmaceutical and biopharmaceutical science and technology across the region. Highlights will include outcomes from recent scientific events, regulatory engagement, and member-driven projects that reflect the Chapter’s commitment to innovation and professional development, including the new to launch PDA

09:00 – 09:15	09:00 – 09:15	SECP Mentoring Program. The session will also explore global PDA developments, showcasing opportunities for international collaboration and engagement. Whether you are a long-standing member or newly involved with PDA, this update will offer valuable perspectives on how local and global efforts are shaping the future of the industry. • **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** Recent articles and discussions have pointed to limitations of advancement in equipment and primary packaging components as hurdles to implementation of Annex 1 principles. Moving control of sterile components to the Contamination Control Strategy of pharmaceutical manufacturers has resulted increased focus on compliance to Annex 1 for RTF component manufacturing. The result of these factors is a call to action for the primary packaging suppliers to improve offerings and compliance. This presentation will provide an overview of implementation at a supplier as a case study to support this call to action. This presentation will discuss the types of improvements required within the primary packaging space to support customers in achieving these objectives • **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** The revised EU GMP Annex 1 implemented in August 2023 contains new requirements for the container closure of sterile pharmaceutical products. These requirements have triggered new best industry practices in the area of container closure integrity testing. This presentation will review the container closure requirements and describe a practical road map enabling compliance. This includes the following: • Implement a deterministic analytical method for container closure integrity testing. • Such a method enables the generation of robust science-based container closure data in a product life cycle approach as required by the EU GMP Annex 1. • Design packaging studies which a) demonstrate the achievement and maintenance of good container closure, and b) identify any risks to CCI and enables the definition of an appropriate testing strategy. • **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	
	11:00 – 11:05	**Welcome Remarks** • **Jo Sherriff** , Engineering Compliance Manager, *SeerPharma Pty. Ltd.*
		Cleaning Classified Rooms to meet EU Annex 1 requirements The presentation will bring clarity to the cleaning and disinfection process by covering current industry trends, global regulatory expectations, and essential elements needed to keep the cleanroom in a state of control. Cleaning and Disinfection is a critical component of the contamination control program during a pandemic. There will be an in-depth discussion on current regulations, disinfectant and sterilant

	11:05 – 11:30	technologies, operator safety, and applications of these products. Application methods, rotation and cleaning frequencies will be covered. Current industry trends in disinfectant rotation, sterility, application techniques, and rinsing will be discussed. Regulatory expectations of FDA, MHRA, ANVISA, ANMAT, HPRA, EMA, and ANSM inspectors will be discussed. The new Annex I, USP 43 <1072>, PDA Technical Report #70 and other industry guidance documents will be covered as they relate to cleaning and disinfection. The attendees will gain a stronger understanding of current industry trends regarding materials transfer, cleanroom cleaning and cleaning of RABS and Isolators. Current industry FDA Warning Letters and FDA 483s will be covered as teaching tools. • **James N. Polarine MA**, Principal Consultant, *STERIS*
11:00 – 12:35	11:30 – 11:55	**GMP Myth Busting** For millennia, myths and legends have provided “answers” to questions that couldn’t otherwise be explained. The scientific revolution only occurred a few hundred years ago, but since then our understanding of the universe, from the micro to the macro, has expanded exponentially. Thankfully, our world of manufacturing medicine is securely founded on facts and figures backed by science. Or is it? Let’s take a closer look at some commonly held beliefs we are familiar with and see if they are really supported by data. • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva*
	11:55 – 12:20	**Aseptic Processing – Emerging expectations or a paradigm shift?** This will be a discussion on selected FAQs arising from industry based on inspection activities or GMP topics raised at industry forums, after Annex 1 Implementation (in EU) in August 2023. The views that follow were aired at a PDA Annex 1 Implementation, GxP Auditing & Inspections, & Sterile Processing Joint Interest Group Virtual Meeting on 2nd October 2024. • **Bruce Loxley** , Science Advisory Board member 2022-2028, *PDA*
	12:20 – 12:35	**Panel Discussion and Q&A**
12:35 – 13:35	**Lunch Break**	
	Session 6- QC Innovation Spotlight: Case Studies in Advanced Testing for Sterility Assurance	
13:35 – 14:50	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 at CSL Seqirus, presents a case study on the optimisation of the BioFire® FilmArray 2.0 system for Mycoplasma detection. Traditional compendial methods require up to 28 days for results, whereas the BioFire system delivers same-day automated, nucleic acid-based results. Feasibility studies confirm the system’s sensitivity at ≤10 CFU/mL, meeting EP and USP standards. The technology, at a first glance, demonstrates specificity and comparability to existing methods, supporting preliminary suitability for pharmaceutical quality control. Its rapid turnaround has potential to significantly enhance manufacturing efficiency, particularly in time-sensitive processes such as seasonal influenza vaccine production. • **Melissa Damino** , Director of Quality Control, Tullamarine, *CSL Seqirus*
	13:55 – 14:10	**Case Study - rFC Endotoxin Testing** Endotoxin testing is a critical quality control measure in pharmaceutical and clinical trial environments, traditionally performed using Limulus Amebocyte Lysate (LAL) assays. However, the emergence of recombinant Factor C (rFC) technology offers a synthetic, animal-free alternative with enhanced sensitivity and specificity. This case study explores the scientific basis and operational advantages of rFC-based endotoxin assays, highlighting their performance in detecting low-level endotoxin contamination across diverse sample matrices. We will present data demonstrating the improved sensitivity of rFC assays in complex formulations and biologics. The discussion will include validation strategies, regulatory acceptance, and implementation considerations for laboratories transitioning to rFC platforms. By reducing variability and eliminating reliance on horseshoe crab blood, rFC testing supports both sustainability and precision in endotoxin

		detection. • **Robyn Hofer** , Operations Manager, *CBE Pure Solutions*
	14:10 – 14:25	**Case Study - Implementation of Automated EM Plate Reader** At Pfizer Melbourne, the QC Microbiology laboratory manually reads approximately 88,000 environmental monitoring (EM) plates each year. To enhance efficiency, ensure compliance, and simplify workflows, the laboratory sought to identify technology that could automate this process. • **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** This presentation explores Pre-Use Post-Sterilization Integrity Testing (PUPSIT), its regulatory context, and industry concerns. It looks at available data on the subject and how manufacturers can achieve compliance using Quality Risk Management (QRM). Key focus areas include filter flaw masking, sterility assurance, and implementation challenges. The session highlights accepted approaches and how risk-based strategies can support robust, compliant sterile filtration processes aligned with Annex 1 expectations. • **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*
	16:10 – 17:00	**Expert Panel Discussion and Q&A** • **Tracy Moore** , CEO, *TM Pharma Group* • **Matt Davis** , Director, Inspections Section - Manufacturing Quality Branch, *Therapeutic Goods Administration* • **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*	