ISPE Australasia Affiliate

The Australasian Affiliates of ISPE and PDA invite you to attend a joint industry seminar:

PDA Parenteral Drug Association Australia Chapter

Current & Emerging Technologies in Sterile Manufacturing

23 - 24 May 2023
Novotel on Collins
270 Collins Street, Melbourne

About the event

The ISPE Australasian Affiliate and PDA Australia Chapter are excited to be back collaborating on an in-person event in Melbourne, Current & Emerging Technologies in Sterile Manufacturing.
This year we bring you international experts representing our leading industry associations who will share their experience on how the pharmaceutical industry is evolving, adopting new technologies and increasing demand for personalised medicines and Advanced Therapeutic Medicinal Products (ATMPs).
We will look at the impact to and current feedback from industry on the revised Annex 1 requirements, as well as the use of exciting technologies such as Isolators, Robotic Systems, Augmented Reality (AR) and Rapid Microbial Methods (RMM).
This event provides the ideal forum to discuss the current and emerging regulatory requirements and technologies used in sterile manufacturing, and the challenges and opportunities these present.

Key Speakers

Jörg Zimmermann is currently Vice President External Affairs for Vetter Pharma Fertigung GmbH&Co KG, Ravensburg, Germany.
Jörg has been with Vetter for over 20 years where he has held various positions including overseeing drug development activities such as manufacturing science & process development, technology & process transfers, project & service analytics and drug delivery systems. During his time at Vetter's production site at Lake Constance he was responsible for process implementation, new product introduction, lyophilization process development and managed 5 production lines for aseptically pre-filled injection systems as the Director of Production.
In his current role, he manages relationships with regulatory agencies, professional organisations and other partners in the pharmaceutical industry. Having studied pharmacy in Freiburg, Germany and Cardiff, Wales he is also a registered pharmacist.
Jörg has volunteered as conference chair, track leader and speaker at conferences by ISPE, PDA, and Concept Heidelberg for over 20 years. In 2016, Jörg was elected to the International Board of Directors of ISPE. He is the immediate past Chair to the International Board of Directors and a member of the Executive Committee.

Ivy Louis is the Founder of VIENNI TRAINING & CONSULTING LLP, holds a Master's degree in Pharmaceutical Sciences and an MBA in Human Resource Management.
Ivy's combined 33 years spanning across teaching, pharmaceutical manufacturing, quality, and service provider experience is distilled into the consultative and educational approaches that her organization-VIENNI Training & Consulting LLP has been delivering from 2010 onwards. The areas of support for pharmaceutical and biopharmaceutical operations rests on building excellence through consulting in parenteral operations and catering to the learning requirements for operating personnel through training & education.
Ivy has been a part of the PDA community for over 20 years, during this time she has been instrumental in establishing the PDA India Chapter of which she was a board member from 2013 to 2019. She has volunteered her time to the Steering Committee for Awards in 2017, the Steering Committee for the PDA Letter Editorial Committee and is currently a member of the Task Force working on an ANSI standard for Quality Risk Management for Aseptic Processing. Ivy is also a member of the Science Advisory Board and has recently joined the Board of Directors for PDA Inc.

Date

Tuesday 23 & Wednesday 24 May 2023

Location

Novotel on Collins, 270 Collins Street, Melbourne Victoria 3000

ISPE Australasia Affiliate

The Australasian Affiliates of ISPE and PDA invite you to attend a joint industry seminar:

PDA Parenteral Drug Association Australia Chapter

Current & Emerging Technologies in Sterile Manufacturing

23 - 24 May 2023
Novotel on Collins
270 Collins Street, Melbourne

Who should Attend

- Managers and staff who support or are directly involved in the manufacture of sterile medicinal products, medical devices or non-sterile products for which contamination control is important.
- Quality Assurance and Quality Control Personnel, Microbiologists, Sterility Assurance Specialists
- Technical professionals and vendors who provide products and services to support sterile manufacturing operations
- Research professionals interested in translation from research to clinical and commercial operations

Take Back to Your Job

- Understanding of best practice for sterile manufacture and the expectations for compliance with global regulatory requirements
- Feedback from industry and the expected impact from the Annex 1 revision
- An overview of the application of robotics and barrier technologies in aseptic processing
- Approaches on how to modernise sterile manufacturing through modernised microbiology and the streamlined microbiology laboratory with the use of automated testing solutions and rapid microbial methods
- Risk based approaches to aseptic processing in clinical and commercial manufacture
- Knowledge of the challenges and opportunities that ATMP and Cell & Gene therapy products present

Fees

ISPE or PDA Member:	Early Bird* **$950** incl GST	Standard **$1,200** incl GST
Non-Member:	Early Bird* **$1,150** incl GST	Standard **$1,400** incl GST

**Early bird rate available until 24 April 2023*

Booking & Enquiries

Visit here to book online:

https://www.stickytickets.com.au/aavmg/current__emerging_technologies_in_sterile_manufacturing.aspx

Enquiries: Mandy Bromilow manager@ispe.org.au or (ph) +61 447 279 008

Cancellations: ISPE and PDA reserve the right to change the venue or speakers or program from that described. We also reserve the right in our absolute discretion and without further liability to cancel the program, in which case all event fees will be refunded. We do not provide refunds if you cancel as this enables us to keep our costs and prices to a minimum. We suggest you send a replacement.

ISPE & PDA greatly acknowledges the support of our sponsors:

Critical Scientific Solutions

Pharma Tech SYSTEMS

ISPE Australasia Affiliate

The Australasian Affiliates of ISPE and PDA invite you to attend a joint industry seminar:

PDA Australia Chapter

Current & Emerging Technologies in Sterile Manufacturing

23 - 24 May 2023
Novotel on Collins
270 Collins Street, Melbourne

Tuesday 23 May	
8:00am - 8:30am	Registration, tea and coffee
8:30am – 8:45am	Welcome and introductory remarks
Session 1 – Opening Plenary: The future of sterile medicinal products	
8:45am – 10:15am	• **Which Direction is the Pharmaceutical Industry Taking? From Small Molecules to Personalised Medicine** - Jörg Zimmerman, Vetter Pharma • **Fundamental Concepts of Aseptic Technologies and Shifting Paradigms** - Ivy Louis, Vienni Training & Consulting LLP • **Moving Up the Central Dogma and Moore's Law in Biomanufacturing** - Hari Pujar, Flagship Pioneering
10:15am – 10:45am	Break
Session 2 – Controlled Environments	
10:45am – 12:15pm	• **Update to BSC and Clean Room Environments Standards** - Paul Morgan, Critical Scientific Solutions • **How to work with Barrier Technology** - Jörg Zimmerman, Vetter Pharma • **Working with Isolator Technology** - Koji Ushioda, SKAN Japan
12:15 – 1:15pm	Lunch – Sponsored by Pharma Tech
Session 3 – Annex 1 Manufacture of Sterile Medicinal Products	
1:15pm – 3:00pm	• **Annex 1 – Where are we at?** - Jörg Zimmerman, Vetter Pharma • **What have we heard from industry so far?** - Lisa Bennett, SeerPharma • **Facilitated Discussion on the Revised Annex 1 Requirements** - Jörg Zimmerman, Ivy Louis, Lisa Bennett
3:00pm – 3:30pm	Break
Session 4 – Translating new therapies from discovery to commercialisation	
3:30pm – 5:00pm	• **ATMPs: Challenges and Opportunities of Cell & Gene Therapy Products** - Jörg Zimmerman, Vetter Pharma • **Manufacturing Systems for Vaccines and Biopharmaceuticals** - John Power, CSIRO • **Practical Approaches to Phase Appropriate GMP** - Jeff Davies, CBE
5:00pm – 5:15pm	**Day 1 Wrap Up and Closing Remarks**
5:15pm – 7:00pm	Networking drinks & canapés – Hosted by PDA Australia Chapter and ISPE Australasian Affiliate

Schedule times may be varied during the course with the agreement of delegates to ensure content is adequately covered.

ISPE & PDA greatly acknowledges the support of our sponsors:

Allied Scientific PRODUCTS
MasterControl
FLUID biosolutions
wood.

ISPE Australasia Affiliate

The Australasian Affiliates of ISPE and PDA invite you to attend a joint industry seminar:

PDA Australia Chapter

Current & Emerging Technologies in Sterile Manufacturing

23 - 24 May 2023
Novotel on Collins
270 Collins Street, Melbourne

Wednesday 24 May	
8:00am - 8:30am	Registration, tea and coffee
8:30am – 8:45am	Welcome and introductory remarks
Session 5 – Risk Management in Aseptic Processing	
08:45am – 10:00am	• **Small Scale Clinical vs Full Commercial Production: What are the Appropriate Operational and Quality Approaches?** - Jörg Zimmerman, Vetter Pharma • **Risks and Mitigation for Sterile Product Manufacture** - Ivy Louis, Vienni Training & Consulting LLP
10:00am – 10:30am	Break
Session 6 – Environmental Monitoring	
10:30am – 12:00pm	• **A Smart Environmental Monitoring Program - The form & the frame!** - Ivy Louis, Vienni Training & Consulting LLP • **Practical Application and Interpretation of Environmental Monitoring Data,** - Justine Mann, CBE • **Rapid QC Microbiology Testing Through the Lens of Environmental Monitoring – Points for Consideration** - David Franken, Rapid Micro Biosystems
12:00 – 13:00	Lunch – Sponsored by Critical Scientific Solutions
Session 7 – Evolution of the Microbiology Laboratory	
1:00pm – 3:00pm	• **Modernisation of the QC Microbiology Laboratory** - Tara Cassidy, Charles River Laboratories • **Smart Quality Monitoring in the Pharmaceutical Industry** - Juliana Gutierrez, bioMerieux • **Microbiological Control and Management under revised annex 1 regulations** - Michael Payne, MERCK • **Automated Testing Solutions for Accurate and Sustainable Endotoxin Testing** - Alan Hoffmeister, Charles River Laboratories
3:00pm – 3:30pm	Break
Session 8 – Industry 4.0 - The Future is Now	
3:30pm – 5:30pm	• **Innovative Technologies to Support Contamination Control Strategies** o Jason Kavanagh, GCON • **Robots in Aseptic Processing** o Jörg Zimmerman, Vetter Pharma • **Replacing Manual Aseptic Operations with Robotics** o Koji Ushioda, SKAN Japan • **Application of Augmented Reality in the Cleanroom** o Sharon Orr, CSL Innovation
Day 2 Wrap Up and Closing Remarks	

Schedule times may be varied during the course with the agreement of delegates to ensure content is adequately covered.

ISPE & PDA greatly acknowledges the support of our sponsors:

BIOMÉRIEUX charles river MERCK Rapidmicro biosystems®