



Agenda

PDA Annex 1 Workshop 2024

Tuesday, 5 November

08:00 – 18:00

Registration Open

09:00 – 09:10

Welcoming

Committee Member: Falk Klar, PhD, Parenteral Drug Association

09:10 – 09:20

Welcome Remarks from Workshop Co-Chairs

Co-Chair: Tracy Moore, Director, TM Pharma Group Ltd

Co-Chair: Frederic B. Ayers, Senior Consultant - Microbiology, ValSource, Inc.

09:20 – 10:40

P1: EU GMP Annex 1 Implementation – A Regulator’s Perspective

Moderator: Tracy Moore, Director, TM Pharma Group Ltd

10:40 – 11:10

Networking Coffee Break, Poster Session & Exhibition

11:10 – 12:05

P2: Quality Risk Management & Knowledge Management

Moderator: Frederic B. Ayers, Senior Consultant - Microbiology, ValSource, Inc.

11:10 – 11:30

EU GMP Annex 1 and Quality Risk Management

Presenter: Amanda McFarland, MS, Senior Consultant, ValSource, Inc.

11:30 – 11:50

Knowledge Management in Pharmaceutical Manufacturing

Presenter: Melanie Adams



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11:50 – 12:05

Q&A

Moderator: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

Panelist: Amanda McFarland, MS, Senior Consultant, *ValSource, Inc.*

Panelist: Melanie Adams

12:05 – 12:50

Breakout Session 1

12:50 – 13:50

Networking Lunch Break, Poster Session & Exhibition

13:50 – 14:45

P3: Cleanroom Design & Barrier System Integration

Moderator: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

13:50 – 14:10

Cleanroom Design

Presenter: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

14:10 – 14:30

Barrier Systems

Presenter: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions*

14:30 – 14:45

Q&A

Moderator: Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

Panelist: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

Panelist: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions*

14:45 – 15:30

Breakout Session 2



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15:30 – 16:00

Networking Coffee Break, Poster Session & Exhibition

16:00 – 16:55

P4: Decontamination & Material Transfer

Moderator: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, Emergent BioSolutions

16:00 – 16:20

Material Transfer - overcoming the challenge.

Presenter: Laura Brennan, Director of Technical Consulting, Ecolab

16:20 – 16:40

CCS on Indirect Product Contact Surfaces - Transfer and Assembly

Presenter: Richard Denk, Senior Consulting Aseptic Processing & Containment, SKAN AG

16:40 – 16:55

Q&A

Moderator: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, Emergent BioSolutions

Panelist: Laura Brennan, Director of Technical Consulting, Ecolab

Panelist: Richard Denk, Senior Consulting Aseptic Processing & Containment, SKAN AG

16:55 – 17:40

Breakout Session 3

17:40 – 18:00

Day 1 Wrap Up

Presenter: Tracy Moore, Director, TM Pharma Group Ltd

Wednesday, 6 November

19:00 – 22:00

Networking Reception



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08:00 – 17:00

Registration Open

08:20 – 09:15

P5: Personnel

Moderator: Kurt Jaecques, MA, Global Aseptic Technologies Lead Monitoring & Control, *GSK*

08:20 – 08:40

Training & Qualification

Presenter: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions*

08:40 – 09:00

Gowning & Personnel Monitoring

Presenter: Patrick Nieuwenhuizen, MSc, Director Principal Consultant, *PharmaLex Ireland*

09:00 – 09:15

Q&A

Moderator: Kurt Jaecques, MA, Global Aseptic Technologies Lead Monitoring & Control, *GSK*

Panelist: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions*

Panelist: Patrick Nieuwenhuizen, MSc, Director Principal Consultant, *PharmaLex Ireland*

09:15 – 10:00

Breakout Session 4

10:00 – 10:30

Networking Coffee Break, Poster Session & Exhibition

10:30 – 11:25

P6: Aseptic Processing & Pre-Use Post Sterilization Integrity Testing (PUPSIT)

Moderator: Laura Brennan, Director of Technical Consulting, *Ecolab*

10:30 – 10:50



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Aseptic Processing 1

Presenter: Tracy Moore, Director, *TM Pharma Group Ltd*

10:50 – 11:10

Aseptic Processing 2

Presenter: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

11:10 – 11:25

Q&A

Moderator: Laura Brennan, Director of Technical Consulting, *Ecolab*

Panelist: Tracy Moore, Director, *TM Pharma Group Ltd*

Panelist: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

11:25 – 12:10

Breakout Session 5

12:10 – 13:10

Networking Lunch Break, Poster Session & Exhibition

13:10 – 14:25

P7: EM & Airflow Visualization

Moderator: Francesco Cicirello, PharmD, MSc, Senior Director Global BioNTainer Quality Compliance, *BioNTech*

13:10 – 13:30

Environmental and Process Monitoring

Presenter: Kurt Jaecques, MA, Global Aseptic Technologies Lead Monitoring & Control, *GSK*

13:30 – 13:50

Airflow Visualization

Presenter: Patrick Nieuwenhuizen, MSc, Director Principal Consultant, *PharmaLex Ireland*

13:50 – 14:10

Aseptic Process Simulation



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Presenter: Maria Ginnelly

14:10 – 14:25

Q&A

Moderator: Francesco Cicirello, PharmD, MSc, Senior Director Global BioNTainer Quality Compliance, *BioNTech*

Panelist: Kurt Jaecques, MA, Global Aseptic Technologies Lead Monitoring & Control, *GSK*

Panelist: Patrick Nieuwenhuizen, MSc, Director Principal Consultant, *PharmaLex Ireland*

Panelist: Maria Ginnelly

14:25 – 15:10

Breakout Session 6

15:10 – 15:40

Networking Coffee Break, Poster Session & Exhibition

15:40 – 15:45

Passport Raffle

15:45 – 16:45

P8: Contamination Control Strategy

Moderator: Tracy Moore, Director, *TM Pharma Group Ltd*

15:45 – 16:05

Contamination Control Strategy

Presenter: Amanda McFarland, MS, Senior Consultant, *ValSource, Inc.*

16:05 – 16:45

Plenary Discussion

Moderator: Tracy Moore, Director, *TM Pharma Group Ltd*

Panelist: Amanda McFarland, MS, Senior Consultant, *ValSource, Inc.*

Regulatory Panelist: Thomas Vestergaard Pedersen

Regulatory Panelist: Aedin Hogan



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16:45 – 17:00

Day 2 Report Out & Closing Remarks from the Workshop Co-Chairs

Co-Chair: Tracy Moore, Director, *TM Pharma Group Ltd*

Co-Chair: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

17:00 – 17:05

Closing Remarks & Farewell

Committee Member: Falk Klar, PhD, *Parenteral Drug Association*