Agenda

PDA Annex 1 Workshop 2024

Tuesday, 5 November

08:00 – 18:00

Registration Open
Heather Suite B & Foyer

09:00 – 09:10

Welcoming
Heather Suite A

Committee Member: Falk Klar, **PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*

09:10 – 09:20

Welcome Remarks from Workshop Co-Chairs
Heather Suite A

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
Heather Suite A

In this insightful first session, hear the regulatory perspective from esteemed regulatory inspectors Thomas Pedersen, DKMA, and Aedin Hogan, HPRA as they share their experiences and insights on the progress made in applying the Eu GMP Annex 1 over the past two years. This session will also feature a dynamic plenary discussion with the regulatory panelists, alongside renowned industry expert Francesco Cicirello, BioNTech, moderated by former MHRA expert inspector, Tracy Moore.

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

09:20 – 09:45

EU GMP Annex 1, Implementation and Interpretation from an Authority Perspective

Regulatory Presenter: Thomas Vestergaard Pedersen, **Ph.D**, Manager, *Dansih Medicines Authority*

09:45 – 10:10

Two Years On: Progress and Insights on the Application of EU GMP Annex 1

Regulatory Presenter: Aedin Hogan

10:10 – 10:40

Plenary Discussion

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

Regulatory Panelist: Thomas Vestergaard Pedersen, **Ph.D**, Manager, *Dansih Medicines Authority*

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

Regulatory Panelist: Aedin Hogan

10:40 – 11:10

Networking Coffee Break, Poster Session & Exhibition

Heather Suite B & Foyer

11:10 – 12:05

P2: Quality Risk Management & Knowledge Management

Heather Suite A

This session will enhance your understanding and application of Quality Risk Management (QRM) and Knowledge Management (KM) within the framework of Annex 1. This session will provide practical insights and strategies to effectively manage risks and leverage organizational knowledge to ensure compliance and continuous improvement in pharmaceutical manufacturing.

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

11:10 – 11:30

Ensuring Patient Safety: Integrating QRM and Risk-Based Decision Making to Meet Annex 1 Requirements

Presenter: Tiffany A Baker, **MBA**, Consultant, *ValSource, Inc.*

11:30 – 11:50

Knowledge Management in Pharmaceutical Manufacturing

Presenter: Melanie J. Adams, **BSc, HDip**, Associate Director, *MSD*

11:50 – 12:05

Q&A

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

Panelist: Melanie J. Adams, **BSc, HDip**, Associate Director, *MSD*

Panelist: Tiffany A Baker, **MBA**, Consultant, *ValSource, Inc.*

12:05 – 12:50

Breakout Session 1

Heather Suite A

Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P2.

Agenda

PDA Annex 1 Workshop 2024

12:50 – 13:50

Networking Lunch Break, Poster Session & Exhibition

Heather Suite B & Foyer

13:50 – 14:45

P3: Cleanroom Design & Barrier System Integration

Heather Suite A

Aseptic manufacturing facilities come in a variety of shapes and sizes from retrofitting existing to modern facilities equipped with Barrier as RABS and Isolators. This session will look at some of the key design and operational aspects that have been impacted by the EU GMP Annex 1.

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

13:50 – 14:10

Cleanroom Design

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

14:10 – 14:30

Barrier Systems

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

14:30 – 14:45

Q&A

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

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

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

14:45 – 15:30

Breakout Session 2

Heather Suite A

Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P3.

15:30 – 16:00

Networking Coffee Break, Poster Session & Exhibition

Heather Suite B & Foyer

16:00 – 16:55

Agenda

PDA Annex 1 Workshop 2024

P4: Material Transfer & Decontamination

Heather Suite A

Even the best-designed facility can face failure if there is not equal care placed on the controls for the movement of materials into the critical zones. This session will explore key areas of concern around material transfer and decontamination of material and surfaces and will discuss challenges and experiences with the implementation of Annex 1 requirements.

Moderator: Derek I. Duncan, **PhD**, Director Product Lines, *LIGHTHOUSE Instruments*

16:00 – 16:20

Material Transfer – Overcoming the Challenge

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

16:20 – 16:40

Decontamination and Sterilization of Direct and Indirect Product Contact Surfaces

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

16:40 – 16:55

Q&A

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

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

Moderator: Derek I. Duncan, **PhD**, Director Product Lines, *LIGHTHOUSE Instruments*

16:55 – 17:40

Breakout Session 3

Heather Suite A

Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P4.

17:40 – 18:00

Day 1 Wrap Up

Heather Suite A

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

18:40 – 22:00

Networking Dinner - Jameson Whiskey Distillery

Agenda

PDA Annex 1 Workshop 2024

07:30 – 17:30

Registration Open

Heather Suite B & Foyer

08:20 – 09:15

P5: Personnel

Heather Suite A

The revised EU Annex 1 regulation focuses on better managing risks, monitoring, and controlling cleanroom environments. It is an open door that one of the major risks in manufacturing remains inappropriately trained or qualified personnel. EU Annex 1 introduced more stringent requirements that significantly impact training programs for cleanroom personnel. In the following session, we will be providing practical insight into the appropriate personnel & gowning requirements and the development of a personnel monitoring program.

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

08:20 – 08:40

Training and Personnel Qualification

Presenter: Maria Ginnelly, **MA**, Principal Scientist, Aseptic Process Control Sciences, *BMS*

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

Panelist: Maria Ginnelly, **MA**, Principal Scientist, Aseptic Process Control Sciences, *BMS*

09:15 – 10:00

Breakout Session 4

Heather Suite A

Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P5.

10:00 – 10:30

Networking Coffee Break, Poster Session & Exhibition

Heather Suite B & Foyer

10:30 – 11:25

Agenda

PDA Annex 1 Workshop 2024

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

Heather Suite A

Annex 1 details the need to verify the integrity of the sterilizing filter before and after it is used in the manufacturing process. PUPSIT is a critical step to ensure sterility and mitigate risk to the product. This session will delve into how to perform PUPSIT, as well as some of the limitations and challenges to be considered.

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

10:30 – 10:50

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

Heather Suite A

Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P6.

12:10 – 13:10

Networking Lunch Break, Poster Session & Exhibition

Heather Suite B & Foyer

13:10 – 14:25

P7: EM & Airflow Visualization

Heather Suite A

How to do Environmental Monitoring and Aseptic Process Simulation are areas of the Revision of Annex 1 where there have been significant changes. Air visualization studies are also a critical aspect. Taking together their understanding is paramount to controlling the environment and is crucial in adhering to the new annex. The session will share approaches gained during the implementation for meeting practical challenges that companies have faced, including those in atypical situations.

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

Agenda

PDA Annex 1 Workshop 2024

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

Ensuring Excellence: Aseptic Process Simulation and EU GMP Annex 1 Compliance

Presenter: Maria Ginnelly, **MA**, Principal Scientist, Aseptic Process Control Sciences, *BMS*

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, **MA**, Principal Scientist, Aseptic Process Control Sciences, *BMS*

14:25 – 15:10

Breakout Session 6

Heather Suite A

Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P7.

15:10 – 15:40

Networking Coffee Break, Poster Session & Exhibition

Heather Suite B & Foyer

15:40 – 15:45

Passport Raffle

Heather Suite A

15:45 – 16:45

Agenda

PDA Annex 1 Workshop 2024

P8: Contamination Control Strategy

Heather Suite A

Learn about effective strategies for managing contamination control to ensure quality and compliance. Gain valuable perspectives from panelists, including regulatory panelist Thomas Vestergaard Pedersen on the latest trends and challenges in contamination control and regulatory compliance.

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

15:45 – 16:05

Contamination Control Strategy Management

Presenter: Tiffany A Baker, **MBA**, Consultant, *ValSource, Inc.*

16:05 – 16:45

Plenary Discussion

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

Regulatory Panelist: Thomas Vestergaard Pedersen, **Ph.D**, Manager, *Dansih Medicines Authority*

Panelist: Tiffany A Baker, **MBA**, Consultant, *ValSource, Inc.*

Regulatory Panelist: Aedin Hogan

16:45 – 17:00

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

Heather Suite A

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

Heather Suite A

Committee Member: Falk Klar, **PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*