2023 PDA Annex 1 Workshop (Antwerp)
09 – 10 November 2023
Antwerp / Belgium

Thursday, 09 November 2023		**09:00 – 18:40**
09:00	Welcome and Introduction	Falk Klar, *PDA Europe*
09:05	Welcome Remarks from Workshop Co-Chairs	Frederic B. Ayers, *ValSource* Tracy Moore, *TM Pharma Group*
09:20 – 10:40	**P1: Overview of and Revision Process for EU GMP Annex 1** *Over the past four years, the revised EU GMP Annex 1 has gone through multiple sets of industry reviews, comments, and revisions. The current version presents a diverse, international perspective on regulatory expectations, recommendations, and requirements for modern sterile drug and biologic product manufacturing. The revised EU GMP Annex 1 contains a significant amount of new and more detailed content on many topics. It places a heightened emphasis on the use of risk-based assessment and approaches to design and evaluate manufacturing contamination control. This session will provide insights from regulatory authorities involved in the EU GMP Annex 1 development and review process of the revision, with a focus on the evolution, planning, and implementation of these changes.*	**Moderator:** Frederic B. Ayers, *ValSource*
09:20	Update to the Annex 1 Guideline on Manufacture of Sterile Products	**Presenter:** Roberto Conocchia, *EMA* *(remote presentation)*
09:45	U.S. FDA Regulatory Perspective on Sterile Manufacturing and Current Trends in Biologics Inspection Findings	**Presenter:** Derek Smith, *U.S. FDA*
10:10	Q&A and Panel Discussion	
10:40	**Coffee Break, Poster & Exhibition**	
11:10 – 12:25	**P2: Scope, Principles, and Pharmaceutical Quality Systems** *This session opens our in-depth look at the content of the draft EU GMP Annex 1. The Scope, Principles, and Pharmaceutical Quality System sections introduce the vision of the EU GMP Annex 1 changes that track through all other sections. Talks will highlight EU GMP Annex 1 focal points including contamination control strategy, quality risk management, and quality culture, including a discussion on the importance of human factors: knowledge, attitude, and experience. This session will also address the expanded scope of EU GMP Annex 1 to include some non-sterile drug products.*	**Moderator:** Derek Duncan, *LIGHTHOUSE Instruments*
11:10	Using Quality Risk Management to Enable the Contamination Control Strategy	**Presenter:**

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		Amanda M. McFarland, *ValSource*
11:40	Considerations on implications of EU & PIC/S GMP Annex 1 for Advanced Therapy Medicinal Products and Low Bioburden Products	**Presenter:** Francesco Cicirello, *BioNTech (remotely)*
12:10	Q&A, Discussion	
12:25	Transition to Breakout Session	
12:30	**Breakout Session 1** Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P1: Overview of and Revision Process for EU GMP Annex 1 and P2: Scope, Principles, and Pharmaceutical Quality Systems.	
13:10	**Lunch Break, Poster & Exhibition**	
14:10 – 15:25	**P3: Premises and Barrier Systems** *Aseptic manufacturing facilities come in a variety of shapes and sizes, from traditional aseptic through restricted access barrier systems (RABS) and Isolators. This session will look at some of the key design and operational aspects that have been impacted by the revised EU GMP Annex 1.*	**Moderator:** Patrizia Muscas, *Eli Lilly and Company*
14:10	Cleanroom Design: Classification, Qualification, Air Visualization	**Presenter:** Frederic B. Ayers, *ValSource*
14:30	Cleanroom Operation: Disinfection, Transfer of Materials, Monitoring	**Presenter:** David Keen, *Ecolab*
14:50	Barrier Technologies: RABS and Isolators, Glove Integrity, Robotics Decontamination	**Presenter:** Richard Denk, *SKAN*
15:10	Q&A, Discussion	**Moderator:**
15:25	Transition to Breakout Session	
15:30	**Breakout Session 2** Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P3: Premises and Barrier Systems.	
16:10	**Coffee Break, Poster & Exhibition**	
16:40 – 17:55	**P4: Equipment, Technology, and Utilities** *This session will discuss the impact of the EU GMP Annex 1 revision on aseptic manufacturing facilities, specifically focusing on equipment design, indirect product contact parts, such as stopper bowls, and critical utilities, such as water systems.*	**Moderator:** David Keen, *Ecolab*

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16:40	Material Transfer	**Presenter:** Tracy Moore, *TM Pharma Group*
17:00	Decontamination and Sterilization of Direct and Indirect Product Contact Surfaces	**Presenter:** Richard Denk, *SKAN*
17:20	Aseptic Process Simulations	**Presenter:** Patrizia Muscas, *Eli Lilly and Company*
17:40	Q&A, Discussion	
17:55	Transition to Breakout Session	
18:00	**Breakout Session 3** Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P4: Equipment, Technology, and Utilities.	
18:40 – 20:10	**End of Workshop Day 1 & Networking Reception**	

Friday, 10 November 2023		**08:00 – 17:00**
08:00	Welcome and Day 1 Report Out	**Moderator:** Tracy Moore, *TM Pharma Group*
08:20 – 09:15	**P5: Personnel Training, Qualification, Gowning, and Monitoring/Assessment** *Training and qualifying operators are of critical importance to ensuring proper aseptic technique and cleanroom behavior. Routine monitoring of personnel ensures that the qualified personnel are following the established procedures and that they can meet the strict gowning cleanliness requirements during normal operations. Trending and analysis of gloves and gown environmental monitoring (EM) data can provide critical feedback on individual operator performance, potential routes of contamination, specific gowning procedures, and overall training efficacy.*	**Moderator:** Tracy Moore, *TM Pharma Group*
08:20	Qualification and Training	**Presenter:** Patrick Nieuwenhuizen, *PharmaLex*
08:40	Gowning, Personnel Monitoring, and Beyond	**Presenter:** Frederic B. Ayers, *ValSource*
09:00	Q&A, Discussion	
09:15	Transition to Breakout Sessions	
09:20	**Breakout Session 4**	

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	Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P5: Personnel Training, Qualification, Gowning, and Monitoring/Assessment.	
10:00	**Coffee Break, Poster Sessions & Exhibition**	
10:30 – 11:25	**P6: Production Technologies, Part 1** *This session will focus on the EU GMP Annex 1 requirements for aseptic processing and filtration of sterile products. The aseptic processing discussion will address the types of operations and grades needed for aseptic preparation and processing operations. The filtration and sterilization presentation will provide insight into the different types of sterilization and the parameters needed to demonstrate success.*	**Moderator:** David Keen, *Ecolab*
10:30	Aseptic Processing	**Presenter:** Frederic B. Ayers, *ValSource*
10:50	Filtration and Pre-use Post Sterilization Integrity Testing	**Presenter:** Thao Vin Le, *GSK*
11:10	Q&A, Discussion	
11:25	Transition to Breakout Sessions	
11:30	**Breakout Session 5** Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P6: Production Technologies, Part 1 (Aseptic Processing and Filtration and Pre-Use Post Sterilization Integrity Testing).	
12:10	**Lunch Break, Poster & Exhibition**	
13:10 – 14:05	**P7: Production Technologies, Part 2** *This session will introduce some of the more intriguing topics covered and expanded in the revised EU GMP Annex 1, which were selected based on input from the sterile product manufacturing community, as noted during prior meetings and discussions.*	**Moderator:** Amanda M. McFarland, *ValSource*
13:10	Container Closure Integrity Testing and Finishing	**Presenter:** Derek Duncan, *Lighthouse Instruments*
13:30	Production and Specific Technologies (Blow-Fill-Seal, Lyophilization, Single Use System, and Terminal Sterilization)	**Presenter:** Patrick Nieuwenhuizen, *PharmaLex*
13:50	Q&A, Discussion	
14:05	Transition to Breakout Sessions	
14:10	**Breakout Session 6** Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P7: Production Technologies, Part 2 (Container Closure Integrity Testing and Finishing and Production and Specific Technologies (Blow-Fill-Seal, Lyophilization, Single Use System, and Terminal Sterilization).	

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14:50	**Coffee Break, Poster & Exhibition**	
15:20 – 17:00	**P8: Environmental Monitoring and Contamination Control Strategy** *Aseptic Process Simulation (APS) has been identified as one of the key aspects of aseptic process control and monitoring. This session will review the related changes and begin discussing the interpretation and implementation of these recommendations and requirements. The presentations will focus on the EU GMP Annex 1 requirements for APS (media fills) and environmental and process monitoring, including the new requirements and considerations for qualifying and operating a clean area and the extensive new requirements needed to successfully validate an aseptic process.*	**Moderator:** Richard Denk, *SKAN*
15:20	Environmental and Process Monitoring	**Presenter:** Kurt Jaecques, *GSK*
15:40	Contamination Control Strategy Development	**Presenter:** Amanda M. McFarland, *ValSource*
16:00	Q&A & Final Panel Discussion *Join our Discussion with Experts from the Industry and Regulatory:* Frederic B. Ayers, *ValSource* Francesco Cicirello, *BioNTech* Kurt Jaecques, *GSK* Amanda M. McFarland, *ValSource* Tracy Moore, *TM Pharma Group* Derek Smith, *U.S. FDA*	**Moderator:** Richard Denk, *SKAN*
16:40	Day 2 Report Out & Closing Remarks from Workshop Co-Chairs	Frederic B. Ayers, *ValSource* Tracy Moore, *TM Pharma Group*
16:55	Closing Remarks & Farewell	Falk Klar, PDA Europe
17:00	**End of Workshop**	

The agenda is subject to change without notice, Speakers are invited pending confirmation.