



PDA Annex 1 Workshop
05 - 06 November, Dublin, Ireland,
Agenda

Tuesday, 05 November 2024		
09:00	Welcome and Introduction	Falk Klar, <i>PDA Europe</i>
09:10	Welcome Remarks from Workshop Co-Chairs	Fred Ayers, <i>ValSource</i> Tracy Moore, <i>TM Pharma Group</i>
09:20 – 10:40 P1: Annex 1 Implementation – A Regulator’s Perspective		Moderator: Tracy Moore, <i>TM Pharma Group</i>
	<i>Title to be announced</i>	Thomas Pedersen, <i>DKMA</i>
	<i>Title to be announced</i>	Aedin Hogan, <i>HPRA</i>
	Plenary Discussion <i>Join our Discussion with Experts from the Industry and Regulatory:</i> <ul style="list-style-type: none"> - Francesco Cicirello, <i>BioNTech</i> - Aedin Hogan, <i>HPRA</i> - Thomas Pedersen, <i>DKMA</i> 	
10:40	Networking Coffee Break, Poster Session & Exhibition	
11:10 – 12:50 P2: Quality Risk Management & Knowledge Management		Moderator: Fred Ayers, <i>ValSource</i>
	Annex 1 and Quality Risk Management	Amanda McFarland, <i>ValSource</i>
	Knowledge Management in Pharmaceutical Manufacturing	Martin Lipa, <i>GMP Services</i>
	Q&A	
	Breakout Session 1 Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P2.	
12:50	Networking Lunch Break, Poster Sessions & Exhibition	
13:50 – 15:30 P3: Cleanroom Design & Barrier System Integration		Moderator: Richard Denk, <i>SKAN</i>
	Cleanroom Design	Fred Ayers, <i>ValSource</i>



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	Barrier Systems	Marcia Baroni, <i>EBSI</i>
	Q&A	
	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.	
15:30	Networking Coffee Break, Poster Sessions & Exhibition	
	16:00 – 18:00 P4: Decontamination & Material Transfer	Moderator: Marcia Baroni, <i>EBSI</i>
	Material Transfer	Laura Brennan, <i>Ecolab</i>
	Decontamination and Sterilization of Direct and Indirect Product Contact Surfaces	Richard Denk, <i>SKAN</i>
	Q&A, Discussion	
	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.	
	Day 1 Wrap-Up	Fred Ayers, <i>ValSource</i>
18:00 – 19:30	Networking Reception	

Wednesday, 06 November 2024		
08:00	Welcome Back and Day 1 Report Out	Moderator: Tracy Moore, <i>TM Pharma Group</i>
	08:20 – 10:00 P5: Personnel	Moderator: Kurt Jaecques, <i>GSK</i>
	Training & Qualification	Marcia Baroni, <i>EBSI</i>
	Gowning & Personnel Monitoring	Patrick Nieuwenhuizen, <i>PharmaLex</i>
	Q&A	
	Breakout Session 4 Attendees will discuss the implementation challenges, and what can be done to meet those challenges, associated with the topics presented in P5.	
10:00	Networking Coffee Break, Poster Sessions & Exhibition	



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10:30 – 12:10 P6: Aseptic Processing & Pre-Use Post Sterilization Integrity Testing (PUPSIT)		Moderator: Laura Brennan, <i>Ecolab</i>
	Aseptic Processing 1	Tracy Moore, <i>TM Pharma Group</i>
	Aseptic Processing 2	Fred Ayers, <i>ValSource</i>
	Q&A	
	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.	
12:10	Networking Lunch Break, Poster Sessions & Exhibition	
13:10 – 15:10 P7: EM & Airflow Visualization		Moderator: Francesco Cicirello, <i>BioNTech</i>
	Environmental and Process Monitoring	Kurt Jaecques, <i>GSK</i>
	Airflow Visualization	Patrick Nieuwenhuizen, <i>PharmaLex</i>
	Aseptic Process Simulation	Maria Ginnelly, <i>BMS</i>
	Q&A	
	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.	
15:10	Networking Coffee Break, Poster Sessions & Exhibition	
15:40	Passport Raffle	
15:45 – 17:05 P8: Contamination Control Strategy		Moderator: Tracy Moore, <i>TM Pharma</i>
	Contamination Control Strategy	Amanda McFarland, <i>ValSource</i>
	Plenary Discussion <i>Join our Discussion with Experts from the Industry and Regulatory:</i> <ul style="list-style-type: none"> - Aedin Hogan, <i>HPRA</i> - Amanda McFarland, <i>ValSource</i> - Thomas Pedersen, <i>DKMA</i> 	
	Day 2 Report Out & Closing Remarks from Workshop Co-Chairs	Fred Ayers, <i>ValSource</i>



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		Tracy Moore, <i>TM Pharma Group</i>
	Closing Remarks & Farewell	Falk Klar, PDA Europe
17:05	End of Workshop	

The agenda is subject to change without notice, speakers are invited pending confirmation!