

PDA Annex 1 Implementation: Inspection Ready Workshop 2025

Agenda

Tuesday, 17 June

ICT Standard Time (UTC +7:00)

08:00 – 09:00	Registration
09:00 – 10:15	Opening Session
	Introduction by Program Chair 09:00 – 09:15 • Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i>
	Keynote: GMP for ATMPs and Challenges to Implementation 09:15 – 09:45 • Nataporn Iamcholvilert , Professional Pharmacist and GMDP Inspector, <i>Thai FDA</i>
	Q&A Session with FDA Thailand 09:45 – 10:15 • Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i> • Nataporn Iamcholvilert , Professional Pharmacist and GMDP Inspector, <i>Thai FDA</i>
10:15 – 10:45	Coffee Break
10:45 – 12:15	Session 1
	Understanding PIC/s Annex 1, PIC/s Annex 2A for ATMPs and the current revision of the EC/GMP Part IV Guidelines 10:45 – 11:15 • Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i>
	Developing a Robust Contamination Control Strategy (CCS) for Compliance 11:15 – 11:45 • Somasundaram G. , Global Principal Consultant, <i>Merck Life Sciences</i>
	Session 2
11:45 – 12:45	Cleanroom Design and Environmental Monitoring: Meeting Annex 1 Standards 11:45 – 12:15 • Michelle Peake , Senior Consultant, <i>SeerPharma</i>
	Panel Discussion 12:15 – 12:45 • Somasundaram G. , Global Principal Consultant, <i>Merck Life Sciences</i> • Michelle Peake , Senior Consultant, <i>SeerPharma</i> • Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i>
12:45 – 13:45	Lunch Break
PIC/s Annex 1 Workshop/training on CCS-First Air- Barrier and Indirect Product Contact Parts	

13:45 – 15:15	Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i>
15:15 – 15:45	Coffee Break
15:45 – 17:15	PIC/s Annex 1 Workshop/Training Part 2 Somasundaram G. , Global Principal Consultant, <i>Merck Life Sciences</i>

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08:30 – 09:00	Registration
09:00 – 10:10	Session 3
	09:00 – 09:40 Interpreting Regulatory Guidelines for Contamination Control Strategy in Pharmaceutical Manufacturing Wei Xia Ang Ph.D., Senior Regulatory Compliance Lead, <i>Cytiva</i>
	09:40 – 10:10 GMP Inspections: Preparing for Success and Effective Response Strategies Wei Xia Ang Ph.D., Senior Regulatory Compliance Lead, <i>Cytiva</i>
10:10 – 10:40	Coffee Break
10:40 – 11:50	Session 4
	10:40 – 11:20 Driving Efficiency, Flexibility, and Compliance: How MES and EBR Enable Seamless Inspection Teerapong (Jack) Cheepchol , President Software ASIA, <i>Körber Pharma Software Ltd</i>
	11:20 – 11:50 Panel Discussion Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i> Teerapong (Jack) Cheepchol , President Software ASIA, <i>Körber Pharma Software Ltd</i> Wei Xia Ang Ph.D., Senior Regulatory Compliance Lead, <i>Cytiva</i>
11:50 – 13:00	Lunch Break
13:00 – 14:20	Mastering Contamination Control Strategy (CCS) for Annex 1 Compliance Part 1 Alex Tan , Scientific Portfolio Specialist I, <i>Microbial Solutions (Singapore)</i> <i>Charles River</i>
14:20 – 14:50	Coffee Break
14:50 – 16:20	Mastering Contamination Control Strategy (CCS) for Annex 1 Compliance Part 2 Richard Chai , Senior Technical Service Manager, <i>STERIS Corporation</i>