PDA Pharmaceutical Manufacturing & Quality Conference 2025

Agenda

Tuesday, 6 May

SGT Standard Time (UTC +8:00)

08:00 – 09:00	**Registration**	
09:00 – 09:10	**Opening Session**	
	09:00 – 09:10	**Opening Remarks by the Committee Chairperson** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)*
09:10 – 10:25	**Session 1: Regulatory and Industry Session**	
	09:10 – 09:40	**New expectations: MHRA Perspective** • **James Pound** , , *MHRA*
	09:40 – 10:25	**Expert Roundtable: Evolving Nature of Trade Policies – Their Impact on APAC Pharmaceutical Sector** • **Moderator:** • **Andy Hopkins** , Senior Director, *Lachman Consultants* • **James Pound** , , *MHRA* • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)* • **Azwar Kamarudin** , Director, Public Affairs APAC, *Novartis*
10:25 – 11:05	**Coffee Break at the Exhibition Hall**	
11:05 – 12:10	**Session 2: New Modality/Technologies (Part 1)**	
	11:05 – 11:10	**Welcome Remarks by the Moderator** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)*
	11:10 – 11:40	**Factory of the Future - Autonomous Manufacturing** • **Casper Hansen** , CEO and Co-founder, *Technicon A/S*
	11:40 – 12:10	**Cell and Gene Therapy Scale Up: Lessons Learnt from the Semiconductor Industry** • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)*
12:10 – 13:40	**Lunch Break**	
	Session 3: New Modality/Technologies (Part 2)	
		Operational Efficiency In Viral Vector Manufacturing Using AI or New Technologies

	13:40 – 14:10	• **Alan Smith PhD**, Executive Director of Operations Excellence, Biomanufacturing, *Charles River Labs*
13:40 – 15:00	14:10 – 14:40	**Quality Regulatory Considerations for ADCs** • **Wei Xia Ang Ph.D.**, Senior Regulatory Compliance Lead, *Cytiva*
	14:40 – 15:00	**Panel Discussion and Q&A** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)* • **Casper Hansen** , CEO and Co-founder, *Technicon A/S* • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)* • **Wei Xia Ang Ph.D.**, Senior Regulatory Compliance Lead, *Cytiva* • **Alan Smith PhD**, Executive Director of Operations Excellence, Biomanufacturing, *Charles River Labs*
15:00 – 16:05	**Session 4: Operational Excellence in Manufacturing (Part 1)**	
	15:00 – 15:05	**Welcome Remarks by the Moderator** • **Vinny Browning MS**, Executive Director Quality Assurance, *Amgen*
	15:05 – 15:35	**Continuous Improvement Culture** • **Wilbur Ho** , Senior Director of Digital Manufacturing Operations, *MSD*
	15:35 – 16:05	**Revolutionizing Process Design with GenAI: The Kindeva Approach to Manufacturing Excellence** • **Sebastian Scheler MSc**, Managing Director, *Innerspace* • **Jeffrey Gensler** , VP Quality, *Kindeva Drug Delivery*
16:05 – 16:45	**Coffee Break at the Exhibition Hall**	
16:45 – 18:05	**Session 5: Operational Excellence in Manufacturing (Part 2)**	
	16:45 – 17:15	**Regulations for AI application: Do we need more?** • **Sean Tay** , Associate Director Quality Assurance, *Amgen Singapore Manufacturing*
	17:15 – 17:45	**Process Modelling: A Recently Initiated Center of Excellence in Regulatory Science & Innovation(CERSI) in UK with CMAC** • **James Pound** , , *MHRA* • **Daniel Markl** , Associate Director, *Centre for Continuous Manufacturing and Advanced Crystallisation (CMAC)*
	17:45 – 18:05	**Panel Discussion and Q&A** • **James Pound** , , *MHRA* • **Daniel Markl** , Associate Director, *Centre for Continuous Manufacturing and Advanced Crystallisation (CMAC)* • **Jeffrey Gensler** , VP Quality, *Kindeva Drug Delivery* • **Sean Tay** , Associate Director Quality Assurance, *Amgen Singapore Manufacturing* • **Sebastian Scheler MSc**, Managing Director, *Innerspace*

Wednesday, 7 May

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08:00 – 09:00	**Registration**	
09:00 – 10:35	**Session 6: Microbiology (Part 1)**	
	09:00 – 09:05	**Welcome Remarks by the Moderator** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)*
	09:05 – 09:35	**In-Process Controls in Pharmaceutical Production: What to Test and How to Use the Results** • **Miriam Guest** , Senior Principal Scientific Advisor, *Charles River Labs, Microbial Solutions*
	09:35 – 10:05	**Disinfectant Field Study** • **David Keen MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*
	10:05 – 10:35	**Enzyme Indicators – The Approach to H2O2 Bio-decontamination Cycle Development, Qualification and Beyond** • **Kate Marshall** , Technical Director, *Protak Scientific*
10:35 – 11:15	**Coffee Break at the Exhibition Hall**	
11:15 – 12:55	**Session 7: Microbiology (Part 2)**	
	11:15 – 11:45	**The Dynamics Between Microbial Ingress and Container Closure Integrity** • **Noba Ebaid** , Director of Sales, Americas & Asia-Pacific, *PTI – Packaging Technologies & Inspection* • **Wenliang Chen** , APAC BD & Technical Service Manager, *PTI (Packaging Technologies & Inspection)*
	11:45 – 12:15	**Low Endotoxin Recovery Challenge and PDA Technical Report 82 Revision** • **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences*
	12:15 – 12:55	**Panel Discussion and Q&A** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)* • **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences* • **Miriam Guest** , Senior Principal Scientific Advisor, *Charles River Labs, Microbial Solutions* • **David Keen MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences* • **Kate Marshall** , Technical Director, *Protak Scientific*
12:55 – 14:25	**Lunch Break**	
	Session 8: Annex 1 Implementation and Consideration (Part 1)	
	14:25 – 14:30	**Welcome Remarks by the Moderator** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)*

14:25 – 15:30	14:30 – 15:00	**Sterility Assurance – Meeting an Unmet Industry Technical Need on Design and Operation of RABS Systems**
	15:00 – 15:30	**CCS From The Perspective of An ex-regulator. 2 Years Post Annex 1 Where and Why Are We Still Struggling On Implementing** • **Andy Hopkins** , Senior Director, *Lachman Consultants*
15:30 – 16:10	**Coffee Break at the Exhibition Hall**	
16:10 – 17:40	**Session 9: Annex 1 Implementation and Consideration (Part 2)**	
	16:10 – 16:40	**Environmental Monitoring Performance Qualification of New Facilities (EMPQ) in New Facilities: Application of Industry Harmonized Approach** • **Catherine Lefebvre** , Director, Quality Systems & Compliance, *MSD Global Quality Compliance*
	16:40 – 17:10	**Annex 1 Implementation Survey, CCS, ICHQ9(R1)**
	17:10 – 17:40	**Panel Discussion and Q&A** • **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)* • **Andy Hopkins** , Senior Director, *Lachman Consultants* • **Catherine Lefebvre** , Director, Quality Systems & Compliance, *MSD Global Quality Compliance*
17:40 – 17:50	**Closing Remarks** **Li Wei Chan** , Microbiology Manager, *MSD International GmbH (Singapore Branch)*	