PDA Pharmaceutical Manufacturing & Quality Conference 2026

Agenda

Tuesday, 12 May

SGT Standard Time (UTC +8:00)

08:45 – 08:50	**Opening Session**	
	08:45 – 08:50	**Opening Remarks** • **Andy Hopkins** , Senior Director, *Lachman Consultants*
08:50 – 10:40	**Session 1: Opening Plenary**	
	08:50 – 09:20	**Compliance: Regulatory Landscape & Behaviors**
	09:20 – 09:50	**CCS Case Study** • **Miriam Guest** , Senior Principal Scientific Advisor, *Charles River Laboratories*
	09:50 – 10:20	**Knowledge Management (Inspection and Industry)**
	10:20 – 10:40	**Q&A and Panel Discussion**
10:40 – 11:10	**Coffee Break**	
11:10 – 13:00	**Session 2: New Technologies in Manufacturing**	
	11:10 – 11:40	**Manufacturing technologies in the area of drug product filling** • **Tam Lam** , Senior Director, Head of Commercial Drug Product Singapore Site, *WuXi Biologics*
	11:40 – 12:10	**Continuous Manufacturing for Scalable Production for CDMO, Personalized Medicine, and Sustainability** • **Christoph Köth** , Head of GXP Consulting, *Experts Institut Beratungs GmbH*
	12:10 – 12:40	**Contamination Control: From A Manufacturing Perspective** • **Ivin Chew** , Microbiology Technical SME, *Amgen*
	12:40 – 13:00	**Q&A and Panel Discussion**
13:00 – 14:30	**Lunch Break**	
14:30 – 15:50	**Session 3: Annex 1**	
	14:30 – 15:00	**Annex 1 Applicability to Bulk Drug Substance Manufacturing** • **Robert Wittorf** , Senor Director, *Lachman Consultants*
	15:00 – 15:30	**Sterilization and Set Up of Indirect Contact Parts**
	15:30 – 15:50	**Q&A and Panel Discussion**

15:50 – 16:20	**Coffee Break**	
16:20 – 17:40	**Session 4**	
	16:20 – 16:50	**PDA/ANSI 03-2025** • **Brent N. Lieffers** , Senior Director, Innovation Advocacy, *Cytiva*
	16:50 – 17:20	**Advancing Supplier Quality: Strategy, Risk and Partnership in Global Manufacturing** • **Sunny Patel** , Head of Global Supplier Quality, External Quality, *Gilead Sciences*
	17:20 – 17:40	**Q&A and Panel Discussion**

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09:00 – 10:20	**Session 5**	
	09:00 – 09:30	**USP's Environmental Monitoring Documentary and Refence Standards – Current & Future State** • **Edward C. Tidswell PhD**, Executive Director QA, *Merck & Co., Inc.*
	09:30 – 10:00	**Alternative Methods** • **Erika A. Pfeiler PhD**, Senior Consultant - Microbiology, *ValSource, Inc.*
	10:00 – 10:20	**Q&A and Panel Discussion**
10:20 – 10:50	**Coffee Break**	
10:50 – 12:10	**Session 6**	
	10:50 – 11:20	**A Risk Based and Data Driven Approach to Microbial Controls of a High Purity Water System** • **Areen Kalantari** , Global Segment Manager - Pharma & Life Sciences, *Mettler-Toledo Thornton*
	11:20 – 11:50	**WFI by RO, Background and Concerns** • **Andy Hopkins** , Senior Director, *Lachman Consultants*
	11:50 – 12:10	**Q&A and Panel Discussion**
12:10 – 13:40	**Lunch Break**	
13:40 – 15:00	**Session 7**	
	13:40 – 14:10	**Stoppers in Bulk: The Biological Validation of the Sterilization Cycle in Compliance with Current Standards and Regulations.** • **Maria Luisa Bernuzzi PharmD**, Product and Application Engineer, *Mesa Labs*
	14:10 – 14:40	**Enzymatic Indicators (EIs): Case Study**
	14:40 – 15:00	**Q&A and Panel Discussion**
15:00 – 15:30	**Coffee Break**	
	Session 8	

15:30 – 16:50	15:30 – 16:00	**Case Study: Detection of Facultative Anaerobes Contamination in Biological Process**
	16:00 – 16:30	**Case Study: Mold Contamination and Resistance** • **Christian Scheuermann** , Associate Director – Accugenix Global Technical Services, *Charles River Laboratories*
	16:30 – 16:50	**Q&A and Panel Discussion**
16:50 – 17:00	**Closing Session**	
	16:50 – 17:00	**Closing Remarks**