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**

Wednesday, 13 May

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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** The USP Microbiology Expert Committee has responsibility for the revision and generation of more than 70 documentary and reference standards. Many of these collectively shape environmental monitoring expectations across the pharmaceutical industry. This presentation aims to review these current standards in comparison to PDA's TR13. Additionally, exploring key issues, challenges, potential remedies and intended paradigm shifts aimed at advancing risk based, and scientifically meaningful environmental monitoring across the pharmaceutical industry. • **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** This presentation explores a risk-based and data-driven methodology for microbial control within high purity water systems, emphasizing the validation and implementation of an online, real-time microbial analyzer. As microbial contamination risks in high purity water systems directly impact product quality and safety, continuous monitoring and effective control are critical. We detail the validation process of the online microbial analyzer, performed by a third-party laboratory, demonstrating its accuracy, reliability, and compliance with regulatory expectations. Furthermore, a real-world case study illustrates the practical application of this technology, showcasing how data integration and risk assessment inform proactive decision-making and enhance water system management. Attendees will gain insights into leveraging advanced microbial monitoring tools to improve operational efficiency and ensure robust water system control. The presentation aligns with current industry trends emphasizing quality assurance and innovative solutions, providing valuable process knowledge for professionals involved in pharmaceutical manufacturing and quality management. • **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.** Stoppers, commonly used in various pharmaceutical and medical applications, are considered direct contact parts. This classification arises from their role in sealing containers, such as vials, thereby coming into direct contact with the contents they are designed to protect. They are fundamental to maintaining the sterility and integrity of the products they seal. Being direct contact parts, stoppers have stringent quality and cleanliness requirements; they must be free from any microbial contamination to prevent compromising the sterile products they seal. The biological validation of the steam sterilization cycle for stoppers, whether in bulk or in bags, is a complex process and it involves the use of biological indicators to verify the effectiveness of the sterilization process, confirming that all microbial contamination has been effectively eliminated. The main topics of the presentation will be the choice of the proper BI, the rational to justify its choice and use and the correct validation approach based on the load we have to sterilize and on the impact the load will have on the reduction of the microbial charge along the process. • **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**	
15:30 – 16:50	**Session 8**	
	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**