Agenda

PDA Pharmaceutical Manufacturing & Quality Conference 2025

Tuesday, 6 May

08:00 – 09:00

Registration

09:00 – 10:10

Opening Session

Samuel Tan, Head of Operations & Strategy, *Novartis Singapore Pharmaceutical Mfg Pte Ltd*

09:00 – 09:10

Opening Remarks by the Committee Chairperson

Samuel Tan, Head of Operations & Strategy, *Novartis Singapore Pharmaceutical Mfg Pte Ltd*

09:10 – 09:40

Keynote Speech

09:40 – 10:10

New expectations from FDA

10:10 – 10:40

Coffee Break at the Exhibition Hall

10:40 – 12:30

Session 1: New Modality/Technologies

10:40 – 10:45

Welcome Remarks by the Moderator

10:45 – 11:15

Factory of the Future - Autonomous Vaccines Manufacturing

11:15 – 11:45

Antibody-Drug Conjugate (ADC)

11:45 – 12:30

Panel Discussion and Q&A

Agenda

PDA Pharmaceutical Manufacturing & Quality Conference 2025

12:30 – 14:00

Lunch Break

14:00 – 15:35

Session 2: Quality and Regulatory Compliance

14:00 – 14:05

Welcome Remarks by the Moderator

14:05 – 14:35

Bioburden Challenges & Control

14:35 – 15:05

TBC

15:05 – 15:35

Panel Discussion and Q&A

15:35 – 16:05

Coffee Break at the Exhibition Hall

16:05 – 17:35

Session 3: Operational Excellence in Manufacturing

16:05 – 16:10

Welcome Remarks by the Moderator

Samuel Tan, Head of Operations & Strategy, *Novartis Singapore Pharmaceutical Mfg Pte Ltd*

16:10 – 16:40

Continuous Improvement Culture

16:40 – 17:10

Revolutionizing Process Design with GenAI: The Kindeva Approach to Manufacturing Excellence

Sebastian Scheler, **MSc**, Managing Director, *Innerspace*

Jeffrey Gensler, VP Quality, *Kindeva Drug Delivery*

17:10 – 17:40

Panel Discussion and Q&A

Wednesday, 7 May

08:00 – 09:00

Registration

09:00 – 10:35

Session 4: Microbiology Part 1

09:00 – 09:05

Welcome Remarks by the Moderator

09:05 – 09:35

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*

09:35 – 10:05

Sterility Assurance – Meeting an Unmet Industry Technical Need on Design and Operation of RABS Systems

Bruce A. Loxley, Regulatory Inspection Compliance Director, *GSK*

10:05 – 10:35

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*

10:35 – 11:05

Coffee Break at the Exhibition Hall

11:05 – 12:35

Session 5: Microbiology Part 2

11:05 – 11:35

Disinfectant Field Study

11:35 – 12:05

Environmental Monitoring Performance Qualification of New Facilities (EMPQ) in New Facilities: Application of Industry Harmonized Approach

Hillary Chan, Global Sterility Assurance and Microbiology Lead, *Takeda*

12:05 – 12:35

Panel Discussion and Q&A

12:35 – 14:05

Lunch Break

14:05 – 15:05

Session 6: Microbiology Part 3

14:05 – 14:35

Frailty of H2O2 As A Sterilization Method

14:35 – 15:05

TBC

15:05 – 15:35

Coffee Break at the Exhibition Hall

15:35 – 17:05

Session 7: Microbiology Part 4

15:35 – 16:05

Low Endotoxin Recovery Challenge and QC Case Study

Jennifer Cheung, VP of Global Quality Assurance Operations, *Gilead Sciences*

16:05 – 16:35

Sustainability Topics in Microbiology

16:35 – 17:05

Panel Discussion and Q&A

17:05 – 17:15

Closing Remarks