Agenda

PDA Pharmaceutical Manufacturing & Quality Conference 2025

PDA CDMO Partnership Workshop 2025

05 May
Learn More and Register

Tuesday, 6 May

08:00 – 09:00

Registration

09:00 – 09:10

Opening Session

09:00 – 09:10

Opening Remarks by the Committee Chairperson

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

09:10 – 10:40

Session 1: Regulatory and Industry Session

09:10 – 09:40

Keynote Speech: Navigating the Pharmaceutical Landscape - Investment Trends and Opportunities in the Region

Pengfei Chen, Vice President, Healthcare, *EDB Singapore*

09:40 – 10:10

New expectations from FDA

10:10 – 10:40

[Expert Round Table] Evolving Nature of Trade Policies – Their Impact on APAC Pharmaceutical Sector

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

Andy Hopkins, Senior Director, *Lachman Consultants*

Pengfei Chen, Vice President, Healthcare, *EDB Singapore*

Wallace Torres, VP Site Operations, *Amgen Singapore Manufacturing*

10:40 – 11:25

Coffee Break at the Exhibition Hall

Agenda

PDA Pharmaceutical Manufacturing & Quality Conference 2025

11:25 – 12:50

Session 2: New Modality/Technologies

11:25 – 11:30

Welcome Remarks by the Moderator

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

11:30 – 12:00

Factory of the Future - Autonomous Vaccines Manufacturing

12:00 – 12:30

Quality Regulatory Considerations for ADCs

Wei Xia ANG

12:30 – 12:50

Panel Discussion and Q&A

Wei Xia ANG

12:50 – 14:20

Lunch Break

14:20 – 16:15

Session 3: Operational Excellence in Manufacturing

14:20 – 14:25

Welcome Remarks by the Moderator

Vinny Browning, **MS**, Executive Director Quality Assurance, *Amgen*

14:25 – 14:55

Continuous Improvement Culture

14:55 – 15:25

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

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

Jeffrey Gensler, VP Quality, *Kindeva Drug Delivery*

15:25 – 15:55

Regulations for AI application: Do we need more?

Sean Tay, Associate Director Quality Assurance, *Amgen Singapore Manufacturing*

15:55 – 16:15

Panel Discussion and Q&A

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

Jeffrey Gensler, VP Quality, *Kindeva Drug Delivery*

Sean Tay, Associate Director Quality Assurance, *Amgen Singapore Manufacturing*

16:15 – 17:00

Coffee Break at the Exhibition Hall

17:00 – 18:35

Session 4: Annex 1 implementation and consideration

17:00 – 17:05

Welcome Remarks by the Moderator

Li Wei Chan, Microbiology Manager, *MSD International GmbH (Singapore Branch)*

17:05 – 17:35

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*

17:35 – 18:05

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

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

18:05 – 18:35

Panel Discussion and Q&A

Andy Hopkins, Senior Director, *Lachman Consultants*

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

Wednesday, 7 May

08:00 – 09:00

Registration

09:00 – 09:55

Session 5: 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

Annex 1 White Paper

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

09:35 – 09:55

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*

09:55 – 10:40

Coffee Break at the Exhibition Hall

10:40 – 12:10

Session 6: Microbiology Part 2

10:40 – 11:10

Disinfectant Field Study

David Keen, **MRSB CBiol**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

11:10 – 11:40

Enzyme Indicators – The approach to H2O2 Bio-decontamination cycle development, qualification and beyond

Kate Marshall, Technical Director, *Protak Scientific*

11:40 – 12:10

Panel Discussion and Q&A

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

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*

12:10 – 13:40

Lunch Break

13:40 – 14:44

Session 7: Microbiology Part 3

13:40 – 14:10

H2O2 As A Decontamination Method

Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

14:10 – 14:40

The Dynamics Between Microbial Ingress and Container Closure Integrity

14:40 – 15:25

Coffee Break at the Exhibition Hall

15:25 – 16:45

Session 8: Microbiology Part 4

15:25 – 15:55

Low Endotoxin Recovery Challenge and QC Case Study

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

15:55 – 16:25

Sustainability Topics in Microbiology

16:25 – 16:45

Panel Discussion and Q&A

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

Richard Denk, Senior Consulting Aseptic Processing & Containment, *SKAN AG*

Edward C. Tidswell, **PhD**, Executive Director QA, *Merck & Co., Inc.*

16:45 – 16:55

Closing Remarks