PDA Manufacturing and Quality Conference

DAY ONE – Tuesday, 6 September 2022

08:30-09:55	**Opening Session**
08:30-08:40	**Opening Remarks**, Emily Cheah, Organizing Committee Chair (Singapore)
08:40-09:10	**EDB Session**, Lee Chee How, EDB Vice President (Singapore)*
09:10-09:40	**BioNTech Session,** Sam Wilkinson, BioNTech*
09:40-09:55	**Q&A and Discussion**
09:55-10:25	Coffee Break
10:25-12:30	**Regulatory Updates I**
10:25-10:30	**Introduction by the Moderator,** Dinesh Khokal, Director, External Affairs, Japac & Intercontinental – LatAm, Amgen (Singapore)
10:30-11:00	**FDA White Paper on Quality Management Maturity/ Metrics,** Wallace Torres, Amgen (Singapore)
11:00-11:30	**ICHQ9 Quality Risk Management,** Rick Friedman, Deputy Director, Office of Manufacturing Quality, Office of Compliance, Center for Drug Evaluation & Research FDA (USA)
11:30-12:00	**Data Governance: Are We Inspection Ready?,** Peter Baker, President, LiveOak Quality Assurance (USA)
12:00-12:30	**Q&A and Discussion**
12:30-13:30	Lunch Break
13:30-15:25	**Regulatory Updates II**
13:30-13:35	**Introduction by the Moderator**
13:35-14:05	**Annex 1 Changes and Microbiological Expectations,** Andrew Hopkins (UK)*
14:05-14:35	**ECA Guidelines on CCS with Case Studies,** Walid el Azab, STERIS (Belgium)
14:35-15:05	**Upcoming TR on Contamination Control: Equipment Design, Validation and On-Going Control,** Jeff Gaerke*
15:05-15:25	**Q&A and Discussion**
15:25-15:55	Coffee Break
15:55-17:20	**Regulatory Updates III**
15:55-16:00	**Introduction by the Moderator**
16:00-16:30	**PDA TR 60-3: Process Validation A Lifecycle Approach: Annex 2: Biopharmaceutical Drug Substance Manufacturing,** Udesh de Silva, Head of Manufacturing Science & Technology, Shanghai ZhenGe Biotech Co., Ltd. (China)
16:30-17:00	**Implementation of ICHQ5A Recommendations for Biosafety of Medicinal Products: What's New,** Alison Armstrong, Merck KGAA (UK)
17:00-17:20	**Q&A and Discussion**
17:20-18:45	**Digitilization and Advancements**
17:20-17:25	**Introduction by the Moderator** | Moderator: Andiyanto Sutandar (Singapore)
17:25-17:55	**Getting Strategic for a GMP Complaint Paperless System/Manufacturing,** Alvin Peak Hwee Ng, Honeywell (Singapore)
17:55-18:25	**Paperless Laboratory or Digital validation solutions - Data Integrity Enhancements vs Challenges,** Robert Lutskus, Lonza Informatics (USA)
18:25-18:45	**Q&A and Discussion**
18:45	End of Day 1

*Note: * indicates that the speaker's status is not yet confirmed*

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DAY TWO – Wednesday, 7 September 2022

08:30-10:05	**Contamination Control and Microbiology (Part I)**
08:30-08:35	Introduction by the Moderator |
08:35-09:05	**TR88: Microbial Data Deviation**, Marc Glogovsky, Consultant, Valsource (USA)
09:05-09:45	**FDA Guidance on Non-Sterile Pharmaceuticals,** Ziva Abraham, CEO, Microrite (USA)
09:45-10:05	**Q&A and Discussion**
10:05-10:35	Coffee Break
10:35-12:30	**Contamination Control and Microbiology (Part II)**
10:35-10:40	Introduction by Moderator | Emily Cheah, Charles River Labs (Singapore)
10:40-11:10	**TR13: Fundamentals of an EM Programme,** Marc Glogovsky, Consultant, Valsource (USA)
11:10-11:40	**Biofluorescent Particle**, Dawn Watson, Director - Sterile Technology & Commercialization at Merck (USA) & Chan Li Wei, Microbiology Manager, MSD International (Singapore)
11:40-12:10	**GSK - Automation for Endotoxin Testing**, GSK Singapore
12:10-12:30	**Q&A and Discussion**
12:30-13:30	Lunch
13:30-15:25	ATMP
13:30-13:35	Introduction by Moderator
13:35-14:05	**USP New Chapters on Cell and Gene Therapy,** USP
14:05-14:35	**Risk Assessment / Microbiological Quality Control in Cell & Gene Therapy,** David Keen, Ecolab*
14:35-15:05	**J&J: CAR-T Cell QC,** J&J
15:05-15:25	**Q&A and Discussion**
15:25-15:55	Coffee Break
15:55-17:50	Contamination Control / Sterile Processing
15:55-16:00	Introduction by the Moderator
16:00-16:30	**Contamination Control Strategy Case Study,** Chan Li Wei, Microbiology Manager, MSD International (Singapore)
16:30-17:00	**GMP compliance when working with Robotics in Aseptic Processing,** Richard Denk, Senior Consultant Aseptic Processing & Containment, Sales, SKAN AG (Switzerland)
17:00-17:30	**Manual Inspection vs Inspection Supported by AI,** Louis Doneck, Koerber (Germany)
17:30-17:50	**Q&A and Discussion**
17:50-18:00	**Closing Remarks**

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