



8th Advanced GMP Workshop – Virtual

AGENDA (03 – 04 October 2023)

Day 1: Tuesday, 03 October 2023

Session 1 1600 – 1610 hrs	Welcome and Setting the Context Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance
1610 – 1620 hrs	Inaugural Address Nilesh Gupta - Managing Director, Lupin
1620 – 1630 hrs	Keynote Address S Aparna - Secretary, Department of Pharmaceuticals
1630 – 1640 hrs	Opening Address - Current Updates on Regulatory Framework in India A K Pradhan - Joint Drugs Controller (India), CDSCO
1640 – 1650 hrs	Collaboration between IPA and PCI - Way Forward Montukumar Patel - President, Pharmacy Council of India
1650 – 1700 hrs	Opening Address from US FDA Sarah McMullen - Country Director, India Office, Office of Global Operations, US FDA
Session 2 1700 – 1750 hrs	Blueprinting the Future: A Vision for Next-Gen Operations Joe Hughes - Senior Partner, McKinsey & Co.
1750 – 1800 hrs	<i>Break</i>
Session 3	Capability Building
1800 – 1830 hrs	(i) Best Practices – Responding to FDA 483 Inspection Observations Carmelo Rosa - Director Division of Drug Quality, CDER/OMQ FDA
1830 – 1900 hrs	(ii) Cross Contamination Control Strategy with Case Study and regulatory expectations Rahul Songire - Vice President, Central Quality, Zydus Group
Session 4 1900 – 2000 hrs	Panel Discussion on Data integrity within context of Quality Culture <u>Moderator:</u> Shirish Belapure - Senior Technical Adviser, Indian Pharmaceutical Alliance <u>Panelists:</u> <ul style="list-style-type: none">• Samantha Atkinson - Executive Vice President, Principal Consultant, NSF Health Science• Ian Jackson - Unit Manager Inspectorate Risk, Control & Governance, IE&S, MHRA• Jay Jariwala - Senior Director for Regulatory Compliance, Sidley Austin• Amit Sareen - Site Head and Vice President, Manufacturing, Lupin• Pravin Kulkarni - AVP, Halol Site Head Quality, Sterile, Sun Pharma



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Day 2: Wednesday, 04 October 2023

Session 5 1600 – 1640 hrs	Harnessing ERP for enhanced compliance Raghuram Janapareddy - Partner & Managing Director of India, Tenthpin
Session 6 1640 – 1730 hrs	Panel Discussion: Working Towards Ensuring Adequate Drug Supply <u>Moderator:</u> Rajiv Desai - Senior Technical Adviser, Indian Pharmaceutical Alliance <u>Panelists:</u> <ul style="list-style-type: none">• CDR Emily Thakur - Team Leader, Drug Shortage Staff, CDER/DSS, FDA• Pradeep Chakravarty - Executive Vice president of Quality, Lupin• Gaurav Suchak - President & Head of Global Demand & Supply Organization, Zydus• Ranjana Pathak - Global Quality Head, Dr. Reddy's Laboratories
1730 – 1740 hrs	<i>Break</i>
Session 7 1740 – 1820 hrs	Case Study: Transformation through Artificial Intelligence Rajesh Kuppuswamy - Principal, Health Care and Life Sciences, AWS India Private Limited
Session 8 1820 – 1850 hrs	Next frontier of Quality: Illuminating India's Path to Quality Leadership Vivek Arora - Partner, McKinsey & Co
1850 – 1920 hrs	Case Study: Role of Automation and Digitization in Manufacturing and Quality Birendra Singh - President & Global Quality Head, Mankind
Session 9 1920 – 2000 hrs	Future proofing plant operations: Journey so far and opportunities that lie ahead of us Parag Patel - Senior Partner, McKinsey & Co
2000 – 2010 hrs	Vote of Thanks Shirish Belapure - Senior Technical Advisor, Indian Pharmaceutical Alliance