



9th Advanced GMP Workshop – Virtual 22 - 23 October 2024

DRAFT AGENDA

Day 1: Tuesday, 22 October 2024

Session 1 1500 – 1510 hrs	Welcome and Setting the Context Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance (IPA)
1510 – 1520 hrs	Inaugural Remarks Nilesh Gupta - Chair, Quality Forum, IPA and Managing Director, Lupin
1520 – 1535 hrs	Opening Remarks from USFDA Gregory Smith - Country Director, India Office, Office of Global Operations, USFDA
1535 – 1555 hrs	Opening Remarks Rajeev Raghuvanshi - Drugs Controller General (India), CDSCO, Government of India
Session 2 1555 – 1635 hrs	Advancing Operational Excellence through Digitalization Krishna Venkatesh - Head, Global Quality & Pharmacovigilance, Dr Reddy's Laboratories
1635 – 1645 hrs	<i>Break</i>
Session 3 1645 – 1715 hrs	(i) Strategies for Addressing FDA 483 and Warning Letters Guerlain Ulysse - Consumer Safety Officer (Pharmaceuticals), India Office, USFDA
1715 – 1750 hrs	(ii) Data Governance: Regulatory Expectations and Case Studies Ruth Moore - Consumer Safety Officer, OPMA, CDER, USFDA
1750 - 1800 hrs	Q&A Discussion
Session 4 1800 – 1900 hrs	Strengthening Lifecycle Management: Technical & Regulatory Considerations Mahesh Ramanadham - Deputy Director, Office of Policy for Pharmaceutical Quality, OPQ, CDER, USFDA
Session 5 1900 – 2000 hrs	Panel Discussion: Strengthening Quality Assurance in Clinical and BA/BE Studies <u>Moderator:</u> Shirish Belapure - Senior Technical Advisor, IPA <u>Panelists:</u> Rajendra Bangar - Head, Development Quality Assurance, Dr Reddy's Laboratories Arshad Khuroo - Head, Bioavailability and Bioequivalence, Sun Pharma Industries M E Kannan - President & Head, Research & Development, Zydus Lifesciences Samantha Atkinson - Executive VP & Principal Consultant, Lifesciences, NSF Dharmesh Domadia - Head, Global Clinical Operations, Clianza Research



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Day 2: Wednesday, 23 October 2024

Session 6 1500 – 1545 hrs	Revised Schedule M: Driving Regulatory Harmonization S M Mudda - Chairman, Regulatory Affairs, Indian Drug Manufacturers' Association (IDMA)
Session 7 1545 – 1645 hrs	Achieving Operational Excellence through Continuous Manufacturing Rajeev Sinha - Global Chief Manufacturing Officer, Cipla Prashant Sharma - Chief Technical Officer, Zydus Lifesciences Himanshu Gadgil - Chief Executive Officer, Enzene Biosciences
1645 – 1700 hrs	<i>Break</i>
Session 8 1700 – 1730 hrs 1730 – 1800 hrs	Insights from IPA Best Practices Documents Good Engineering Practices Rajendra Kumar Das - Ex-VP of Engineering, Sun Pharma Industries & Founder, EcoVita PAT in Oral Solids and APIs R Kalaiselvan - General Manager, Formulation R&D, Sun Pharma Industries
Session 9 1800 – 1915 hrs	Panel Discussion: Advances in Cleaning Procedures to Minimize Cross Contamination <u>Moderator:</u> Rajiv Desai - Senior Technical Advisor, IPA <u>Panelists:</u> Kellia Hicks - Consumer Safety Officer (Pharmaceuticals), India Office, USFDA Ranjana Pathak - Chief Quality Officer, Lupin Pravin Kulkarni - Head, Global Quality Sustainability & Quality Culture, Sun Pharma Industries Vipul Doshi - Corporate Quality & Compliance Officer, Zydus Lifesciences
Session 10 1915 – 1955 hrs	Integrating Sustainability: The Next Frontier for Pharma Geena Malhotra - Ex-Global Chief Technology Officer, Cipla & MD, Signet Excipients
1955 – 2000 hrs	Vote of Thanks Shirish Belapure - Senior Technical Advisor, IPA