

8th Global Pharmaceutical Quality Summit 2023

Patient Centricity: New paradigm of Manufacturing and Quality

Venue: Taj Lands End, Bandra, Mumbai 400050

Agenda*

Day 1: Thursday, 22 June 2023

0800 hrs onwards	Registration and Networking
Session 1 0900 – 0945 hrs	<p>Welcome and Setting the Context Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance</p> <p>Inaugural Address Nilesh Gupta - Chair, Quality Forum, Indian Pharmaceutical Alliance and Managing Director, Lupin</p> <p>Keynote Address S Aparna - Secretary, Department of Pharmaceuticals, Government of India</p> <p>Release of IPA Best Practices Document</p>
0945 - 1000 hrs	Tea / Coffee Break
Session 2 1000 – 1045 hrs	<p>Future of Manufacturing and Operations David Keeling - Senior Partner, McKinsey & Co</p>
Session 3 1045 – 1200 hrs	<p>Video Message of Dr Patrizia Cavazzoni - Director, CDER, USFDA</p> <p>Global View of Regulatory Affairs - Recent Inspection Observations and Trends Moderator: Shirish Belapure - Senior Technical Advisor, Indian Pharmaceutical Alliance</p> <p>Panellists: Rubina Bose – Deputy Drugs Controller India, CDSCO Sarah McMullen - Country Director, India Office, Office of Global Operations, USFDA James Pound – Deputy Director Standards and Compliance, MHRA Thomas Hecker - Inspector, Certification of Substances Department, EDQM</p>
Session 4 1200 – 1245 hrs	<p>Nitrosamine impurities - Update on USP Tools and Solutions Mrunal Jaywant – Vice President, R&D, USP</p>
Session 5 1245 – 1315 hrs	<p>Track and Trace Methodology for Secure Product Shaunak J. Dave - MD & CEO, Antares Vision India Pvt Ltd.</p>
1315 – 1415 hrs	Lunch Break

Session 6 1415 – 1515 hrs	Quality Culture Transformation Samantha Atkinson - Executive Vice President, Principal Consultant, NSF Health Sciences Ranjana Pathak - Global Quality and Pharmacovigilance Head, Dr Reddy's Laboratories
Session 7 1515 – 1615 hrs	Updated EU GMP Annex 1 Guidelines – Current Expectations Thomas Hecker - Inspector, Certification of Substances Department, EDQM Ivy Louis - Member, Board of Directors and Science Advisory Board, PDA Inc.
1615 – 1630 hrs	Tea / Coffee Break
Session 8 1630 – 1745 hrs	Technology Architecture - Best in Class Engineering Controls in Formulations Manufacturing
1745 – 1750 hrs	Day 01 Concluding Address Rajiv Desai - Senior Technical Advisor, Indian Pharmaceutical Alliance
1930 – 2300 hrs	Cocktail Reception & Dinner - All Participants

*Updated as on: 19th June'23

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Day 2: Friday, 23 June 2023

Session 9 0900 – 0945 hrs	Handling OOS Investigations: Regulatory Expectations Dipesh Shah – Consumer Safety Officer, USFDA
Session 10 0945 – 1015 hrs	Technology: Empowering Pharma Manufacturing Umesh Sathe - Vice President and CEO - Process Automation, Siemens
Session 11 1015 – 1100 hrs	Learnings from other industries for futuristic operations Sanjay Sharma – Global Head Operations, Dr Reddy's Laboratories
1100 – 1115 hrs	Tea / Coffee Break
Session 12 1115 – 1200 hrs	Decarbonisation and implications for Pharma industry Maria Fernandez - Partner, McKinsey & Co
Session 13 1200 – 1230 hrs	Continuous Manufacturing - Current Status and Regulatory Expectations Lalit Kumar – Manager, Sun Pharma
Session 14 1230 – 1315 hrs	CEP 2.0 - CEP of the Future Thomas Hecker - Inspector, Certification of Substances Department, EDQM
1315 – 1415 hrs	Lunch Break
Session 15 1415 – 1545 hrs	Establishing a Digital Lighthouse Facility - Case Study Vivek Arora - Partner, McKinsey & Co Geena Malhotra - Global Chief Technology Officer, Cipla Sanjay Sharma – Global Head Operations, Dr Reddy's Laboratories
1545 – 1600 hrs	Tea / Coffee Break
Session 16 1600 – 1730 hrs	Leadership Panel Discussion: Vision 2047- India pharmaceutical industry way forward Moderator: David Keeling - Senior Partner, McKinsey & Co Panellists: Samina Hamied – Executive Vice Chairperson, Cipla Satish Reddy – Chairman, Dr Reddy's Laboratories Nilesh Gupta – Managing Director, Lupin

	Dilip Shanghvi – Managing Director, Sun Pharmaceutical Industries Pankaj Patel – Chairman, Zydus Lifesciences
1730 – 1800 hrs	Special Address Mansukh Mandaviya - Hon'ble Minister for Chemicals & Fertilizers and Health & Family Welfare, Government of India
1800 – 1810 hrs	Concluding Address Nilesh Gupta - Chair, Quality Forum, Indian Pharmaceutical Alliance and Managing Director, Lupin

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