# 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.  

### Session 3  
1800 – 1830 hrs | (i) Best Practices – Responding to FDA 483 Inspection Observations  
Carmelo Rosa - Director Division of Drug Quality, CDER/OMQ FDA  

### Session 4  
1900 – 2000 hrs | Panel Discussion on Data integrity within context of Quality Culture  
Moderator:  
Shirish Belapure - Senior Technical Adviser, Indian Pharmaceutical Alliance  

Panelists:  
- 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 | Harnessing ERP for enhanced compliance  
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<td>1600 – 1640 hrs</td>
<td>Raghuram Janapareddy - Partner &amp; Managing Director of India, Tenthpin</td>
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| Session 6 | Panel Discussion: Working Towards Ensuring Adequate Drug Supply  
|---|---|
| 1640 – 1730 hrs | Moderator:  
Rajiv Desai - Senior Technical Adviser, Indian Pharmaceutical Alliance  
Moderator:  
Rajiv Desai - Senior Technical Adviser, Indian Pharmaceutical Alliance  
Panelists:  
- 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 | Break |

| Session 7 | Case Study: Transformation through Artificial Intelligence  
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<td>1740 – 1820 hrs</td>
<td>Rajesh Kuppuswamy - Principal, Health Care and Life Sciences, AWS India Private Limited</td>
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| Session 8 | Next frontier of Quality: Illuminating India's Path to Quality Leadership  
|---|---|
| 1820 – 1850 hrs | Vivek Arora - Partner, McKinsey & Co  
Case Study: Role of Automation and Digitization in Manufacturing and Quality  
Birendra Singh - President & Global Quality Head, Mankind |

| Session 9 | Future proofing plant operations: Journey so far and opportunities that lie ahead of us  
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<td>1920 – 2000 hrs</td>
<td>Parag Patel - Senior Partner, McKinsey &amp; Co</td>
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| 2000 – 2010 hrs | Vote of Thanks  
Shirish Belapure - Senior Technical Advisor, Indian Pharmaceutical Alliance |