



10th Advanced GMP Workshop
20-21st November 2025
 AGENDA
 (As on 14.11.2025)

Day 1: Thursday, 20 November 2025

Session 1	
1500 – 1510 hrs	Welcome & Vision for Indian Pharma Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance (IPA)
1510 – 1520 hrs	Inaugural Remarks: A Decade of Quality Nilesh Gupta - Chair, Quality Forum, IPA and Managing Director, Lupin
1520 – 1535 hrs	Opening Remarks from the USFDA Gregory Smith - Country Director, India Office, Office of Global Operations, USFDA
1535 – 1555 hrs	Keynote Address: The Indian Pharma Vision Rajeev Raghuvanshi - Drugs Controller General (India), CDSCO, Government of India
Session 2	Driving Next-Gen Manufacturing
16:00 – 16:55 hrs	Responsible by Design: Embedding Water Sustainability in Pharma. Geena Malhotra – Managing Director, Signet Excipients
17:00 – 17:50 hrs	Continuous Manufacturing: Opportunities and Challenges Amol Kulkarni – Chief Scientist, CSIR-National Chemical Laboratory (NCL), Pune
17:50 – 18:00 hrs	Break
Session 3	AI & Automation in Pharma: What's Next?
18:00 – 18:30 hrs	Considerations for use of AI and related technologies in Pharmaceutical Manufacturing Rajesh Kuppuswamy – Industry Life Sciences and Healthcare Consultant
18:30 – 19:00 hrs	Trust, Traceability AND Transformation: What the next era of AI means for gxp Pharma Anil Chandrupatla– Founder & CEO, Litewave AI
Session 4	
19:00 – 20:00 hrs	Panel Discussion: Biosimilars in India: Scaling with Quality & Speed <u>Moderator:</u> Rustom Mody – Sr. Vice President and Head R&D (Biologics) at Sun Pharma <u>Panellists:</u> Sanjay Singh – CEO & Whole-time Director, Gennova Biopharmaceuticals Mina Grguri – Biosimilar Policy & Science Officer, Medicines for Europe Sanjeev Kumar – President, Zydus Lifesciences Dhananjay Patankar – Ex-Vice President, Syngene

Day 2: Friday, 21 November 2025

Session 1	Advanced Facility & Process Design
15:00 – 16:00 hrs	Designing for Potent Products: OEL-Driven Facility Design Birendra Singh – Senior President of Quality and Compliance, Mankind Vishant Naik – Project Director, Arnita SEZ Consultants
16:00 – 17:00 hrs	Sterility by Design: Qualification & Validation of Isolator Systems Vikram Shukla, President – Parenteral Operations, Zydus Lifescience
Session 2	Capability Building
17:00 – 17:30 hrs	PAGE Foundation: Building Tomorrow's Quality Leaders Amitava Saha – CEO, PAGE Foundation
17:30 – 18:00 hrs	Role of Academia in Quality Ecosystem Manisha Shridhar – Regional Advisor, World Health Organization
18:00 – 18:10 hrs	Break
18:10 – 18:55 hrs	Human Side of Good Manufacturing Practices (GMP) Kiran Jadhav, Associate Director, Kaizen Institute South Asia
Session 3	
18:55 – 19:55 hrs	Panel Discussion: Inspection Insights: Global Regulator Expectations in India <u>Moderator:</u> Shirish Belapure – Senior Technical Advisor, Indian Pharmaceutical Alliance <u>Panellist:</u> Jay Jariwala - Founder and President of Pharmasure LLC, Ex- US FDA Ian Jackson - Expert GMP Inspector, MHRA, UK Robert J. Ham – Senior Consumer Safety Officer, OII, US FDA Krishna Venkatesh - Global Head Quality & Pharmacovigilance, Dr. Reddy's Laboratories
19:55 – 20:00	Vote of Thanks Rajiv Desai – Senior Technical Advisor, Indian Pharmaceutical Alliance