

भारतीय भेषजी परिषद् (स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत सांविधिक निकाय) भारत सरकार आई-300, तीसरी मंजिल, टावर-1, वर्ल्ड ट्रेड सेंटर, नौरोजी नगर, नई दिल्ली-110029 टेलीफोन नंबर 011-65218900-01 E-mail: registrar@pci.nic.in	 कामधे दू, बलवानानम्, प्राणिनामार्तिनाशनम्	PHARMACY COUNCIL OF INDIA (Statutory body under Ministry of Health & Family Welfare) Government of India I-300, 3rd floor, Tower-I, World Trade Centre, Nauroji Nagar, New Delhi-110029 Telephone No. 011-65218900-01 E-mail: registrar@pci.nic.in
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Ref. No. 14-460/2025-PCI

Date.17.11.2025

To

All Institutions approved by the PCI -

a) u/s 12 of the Pharmacy Act, 1948

b) conduct of course

Sub.: Participation of Pharmacy Institutions in the 10th Edition of the Advanced GMP Workshop scheduled to be held on 20th & 21st November, 2025 by Virtual Mode.

Sir/Madam,

With reference to the subject cited above, it is informed that the Indian Pharmaceutical Alliance (IPA) is invited for the 10th Edition of the Advanced GMP Workshop as per following schedule –

Date: 20th – 21st November 2025

Time: 3:00 PM – 8:00 PM IST

Mode: Virtual

Register now: <https://tinyurl.com/mtr6pffr>

Further, please find attached herewith the detailed agenda for the 10th Edition of the Advanced GMP Workshop scheduled to be held on 20th & 21st November, 2025 as received from IPA.

All Pharmacy Institutions are requested to participate in the workshop.

Your kind support is solicited in the matter.

Yours faithfully

(ANIL MITTAL)

Registrar-cum-Secretary



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 Modi – 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