

ADVANCED GMP WORKSHOPS 2017

Chandigarh : 06 - 07 November 2017
Ahmedabad : 09 - 10 November 2017

Goa : 13 - 14 November 2017
Hyderabad : 16 - 17 November 2017

About the Workshop

The United States Food and Drug Administration's (USFDA) India Office, the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA) and the Government of India's Central Drugs Standards Control Organization (CDSCO) in association with Indian Pharmaceutical Alliance (IPA) will conduct the second in a series of workshops in four cities as noted above for the drug industry and regulators from the CDSCO.

Topics

Day 1

- Quality Systems
- Introduction to Data Reliability
- Regulatory Expectations for Data Collection, Storage, Validation and Verifications
- Data Validation

Day 2

- Data Quality and Integrity Investigation in Labs
- Data Quality and Integrity Investigations in Manufacturing and Documentation Practices
- Current Trends in Data Quality and Integrity Issues in Inspections and Risk Based Approach to Investigations
- What is Industry Doing and Needs to Do?

Who Can Participate?

The workshop is for supervisory and middle level managers in manufacturing, quality and regulatory functions in industry and the CDSCO nominees.

Speakers

USFDA

- Dr Carmelo Rosa
- Mr Thomas Arista
- Dr Ademola Daramola
- Dr Krishna Ghosh

MHRA

- Mr Mark Birse
(Chandigarh & Ahmedabad)
- Mr Richard Andrews
(Goa & Hyderabad)

EMA

- Dr Patrick Costello

In Collaboration With



For more information about the conference, please visit www.ipa-india.org
For registration write to archana.jatkar@ipa-india.org