

**USP Pharmaceutical Continuous Manufacturing (PCM)--Technology
Development and Implementation Workshop**
May 16, 2017
ITC Maratha Hotel, Mumbai

Agenda

Tuesday, May 16

Pharmaceutical Continuous Manufacturing (PCM) Research, Development and Application

- 7:30 a.m. Breakfast
- 8:30 a.m. Welcome Address
Dr. Sameer G Navalgund – VP, USP India Site Head
- 8:35 a.m. Workshop Opening
Dr. Ajaz Hussain—*Workshop Facilitator; NIPTE*
- 8:40 a.m. Welcome address
Dr. Satyanarayana Chava, CEO, Laurus Labs, and USP Board Member
- 8:55 a.m. Opening Remark
Dr. Jaap Venema – *Chief Science Officer, USP*
- 9:15 a.m. Defining Pharmaceutical continuous manufacturing (PCM):
what are the technological components & integration?
Dr. Fernando Muzzio – *Director, C-SOPS, and Distinguished Professor, Rutgers University*
- 10:05 a.m. PCM Capability Buildup: hardware and software
Dr. Doug Hausner –*Associate Director, C-SOPS, Rutgers University*
- 10:55 a.m. Break
- 11:10 a.m. Continuous Pharmaceutical Manufacturing: Quality and Reliability from Process Understanding
Dr. Bill Randolph-*VP, Strategic Manufacturing, Janssen Pharmaceuticals, J&J*

- 12:00 p.m. Regulatory Opportunities in Continuous Manufacturing
Dr. Leslie Weiss —*Director, CMC Regulatory Affairs, J&J*
- 12:50 p.m. Lunch
- 1:40 p.m. Continuous Manufacturing as a Strategic Initiative for USP
Dr. Ding Ming—*VP, Research & Innovation, USP*
- 2:10 p.m. Continuous Manufacturing: A Key Emerging Technology for Pharmaceutical Modernization (Video Recording)
Dr. Sau Lee—*Head of ETT/OPQ/CDER/FDA, US FDA*
- 2:50 p.m. Networking Break
- 3:20 p.m. Pharmaceutical Manufacturing development at India-- Past, Current, and Future: Promises and Challenges to adopt PCM for quality advancement and cost reduction
Dr. Ajaz Hussain— *Workshop Facilitator; NIPTE*
- 4:10 p.m. Open Discussion-Local Industry Panel & Q&A from US FDA (Dr. Sau Lee) via Webex
Moderator: Dr. Ajaz Hussain – *Workshop Facilitator; NIPTE*
- Where we are in global PCM research, development, & implementation
 - What is needed to accelerate the transition in India
 - How USP, FDA, and Others can help
- 5:40 p.m. Closing Remarks
Dr. Jaap Venema – *Chief Science Officer, USP*
Dr. Sameer G Navalgund – *VP, USP India Site Head*
- 6:00 p.m. High Tea Reception