

"Towards Excellence in Quality" AGENDA*

DAY 1: 23 FEBRUARY 2017

0800 Onwards	Registration and Networking
Session 1 0900 - 1030 hrs	Inaugural Address Mr Nilesh Gupta - President, Indian Pharmaceutical Alliance Keynote Address Ms Mary Lou Valdez - Associate Commissioner and Director of the Office of International Programs Opening Remarks Dr Mathew T Thomas - Director, USFDA India Office Ms Caroline Le Tarnec - Head Public Relations & Documentation Division, EDQM Mr Gerald W Heddell - Director of Inspection, Enforcement & Standards, MHRA Mr Brendan Cuddy - Head of Manufacturing and Quality Compliance, EMA Dr G N Singh - Drugs Controller General of India, CDSCO The Conference Agenda and Setup Mr Dilip G Shah - Secretary General, Indian Pharmaceutical Alliance
Session 2 1030 - 1115 hrs	Reflections on Journey So Far Mr Vikas Bhadoria - McKinsey & Co Release of IPA Data Reliability Guidelines Mr K L Sharma - Joint Secretary, DoH&FW Report Highlights: Dr Jaidev Rajpal - McKinsey & Co and IPA QF Representative
1115 - 1130 hrs	Networking Tea/Coffee
Session 3 1130 - 1215 hrs	EMA's Guidance on Data Integrity Mr Brendan Cuddy - Head of Manufacturing and Quality Compliance, EMA Q&A
Session 4 1215 - 1300 hrs	India's Drug Regulatory Reforms Anchor: Dr G N Singh - DCGI, CDSCO Dr V G Somani - New Drug Approval & Post Marketing Surveillance Dr R Chandrashekar - E-Governance Mr A K Pradhan - Patient Safety
1300 - 1400 hrs	Networking Lunch
Session 5 1400 - 1530 hrs	Building a Strong Quality Culture and Line Ownership Mr David Keeling - McKinsey & Co and IPA QF Representative Ms Alicia Mozzachio - Senior Advisor, International Activities (OPPQ), USFDA Mr Gerald W Heddell - Director of Inspection, Enforcement & Standards, MHRA Q&A
1530 - 1600 hrs	Networking Tea/Coffee
Session 6 1600 - 1800 hrs	Investigation of Non-conformances Mr Kartik Reddy - McKinsey & Co and IPA QF Representative Batch Failure Investigation Ms Alicia Mozzachio - Senior Advisor, International Activities (OPPQ), USFDA Mr Mark Birse - Group Manager Inspectorate, MHRA Q&A
1930 - 2300 hrs	Cocktail Reception & Dinner - All Participants

*Subject to change without prior notice.