

6th India Pharmaceutical Forum

Patient centricity: New Paradigm in Quality Management

Tentative Agenda (24 – 26 February 2021)

Day 1: 24 February 2021

Session 1 1600 – 1700 hrs	Welcome and Setting the Context Mr Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance Inaugural Address Mr Satish Reddy – President, Indian Pharmaceutical Alliance Opening Address Dr V G Somani – DCG(I) Keynote Address and inauguration of IPA Best Practices Document Ms S Aparna – Secretary, Department of Pharmaceuticals (DoP)
Session 2 1700 – 1715 hrs	Video Message on Pharmaceutical Quality Dr Theresa Mullin - Associate Director for Strategic Initiatives, CDER, USFDA
Session 3 1715 – 1800 hrs	International Commitment to Pharmaceutical Quality Dr Michael Kopcha - Director Office of Pharmaceutical Quality (OPQ), USFDA
1800 – 1815 hrs	Tea / Coffee Break
Session 4 1815 – 1945 hrs	Virtual / Remote Inspections Observations and Findings Dr Cristina Baccarelli – GMP Inspector, EDQM Ms Paula Walker - Deputy Group Manager, Inspectorate, MHRA Inspection during COVID-19 and overview of GDUFA III negotiations Mr David Gaugh - Senior VP for Sciences and Regulatory Affairs, AAM
Session 5 1945 – 2030 hrs	Panel Discussion - New paradigm in Quality Management Moderator: Mr Shirish Belapure – Senior Technical Advisor, Indian Pharmaceutical Alliance Dr Deus Mubangizi - Group Lead, Inspection Services, PREQUAL Team, WHO Dr Cristina Baccarelli – GMP Inspector, EDQM Dr Rubina Bose – Deputy Drugs Controller (India), CDSCO (West)

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Day 2: 25 February 2021

Session 6 1600 – 1630 hrs	Environment, Health and Safety (EHS) and Sustainability Mr Koen Laenen - Senior Manager, Quality and Regulatory Affairs, Medicines for Europe
Session 7 1630 – 1800 hrs	Global view on Regulatory Affairs Moderator: Dr Rajiv Desai – Executive VP Corporate Quality and Assurance Ms Beata Stepniewska - Deputy Director General & Head of Regulatory Affairs, Medicines for Europe Mr Anthony Lakavage, Senior Vice President, Global External Affairs, USP Mr K S Babu – Head Regulatory Affairs, Pfizer Dr Rajkiran Jain – Senior Vice President – Global Regulatory Affairs, Glenmark
1800 – 1815 hrs	Tea / Coffee Break
Session 8 1815 – 1900 hrs	Contamination Control – Product and Facility Point of View Mr Vipul Doshi – Group President Quality Assurance and IRA, Zydus Cadila
Session 9 1900 – 1930 hrs	Update on USFDA quality standards and the path forward Mr Francis Godwin, Director, Office of Manufacturing Quality, Office of Compliance, USFDA
Session 10 1930 – 2030 hrs	Panel Discussion - Industry – Academia Collaboration Moderator: Dr Y K Gupta – President AIIMS Bhopal, Samba, Jammu Panellists: Dr B Suresh – President, Pharmacy Council of India Dr SJS Flora - Director, NIPER Raebareli/ Mohali Mr Ganadhish Kamat – Global Head of Quality, Dr Reddy's Laboratories Dr Surinder Singh – Vice Chancellor, JSS Mysuru

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Day 3: 26 February 2021

Session 11 1600 – 1630 hrs	Integrated Risk Assessment from design to delivery Dr Ghada Haddad - Executive Director, Global cGMP Compliance and Auditing Organization, Merck & Co.
Session 12 1630 – 1730 hrs	Quality compliance culture & empowerment in the new-normal McKinsey Speaker Dr Ranjana Pathak- President, Global Quality Medical Affairs & Pharmacovigilance, Cipla
Session 13 1730 – 1815 hrs	Panel Discussion: Digitalisation / automation and artificial intelligence in Operations Moderator: McKinsey Expert Panellists: Ms Geena Malhotra – Global Chief Technology Officer, Cipla Mr Rajendra Chunodkar – President Manufacturing Operations, Lupin Mr Jila Breeze – Global Head Quality and Compliance, Sun Pharma Mr Sanjay Sharma – Global Head Operations, Dr Reddy's Laboratories
1815 – 1830 hrs	Tea / Coffee Break
Session 14 1830 – 2000 hrs	CEO Panel Discussion– COVID-19 impact on Pharmaceutical Industry Moderator: Mr Gautam Kumra - Managing Partner - McKinsey & Co. Panellists: Mr Nilesh Gupta, Managing Director - Lupin Ltd Mr Satish Reddy, Chairman - Dr Reddy's Laboratories Ltd Mr Dilip Shanghvi, Managing Director - Sun Pharmaceutical Industries Ltd Mr Pankaj Patel, Chairman - Cadila Healthcare Ltd Mr Samir Mehta, Chairman - Torrent Pharmaceuticals Limited Ms Samina Hamied, Executive Vice Chairperson - Cipla Ltd
Session 15 2000 – 2030 hrs	Closing Remarks Mr Nilesh Gupta – Chair Quality Forum, Indian Pharmaceutical Alliance Vote of Thanks Mr Shirish Belapure – Senior Technical Advisor, Indian Pharmaceutical Alliance