

## Patient Centricity and Integrated Quality Management

### Agenda\*

Day 1: 27 February 2020

<b>0800hrs Onwards</b>	<b>Registration and Networking</b>
<b>Session 1</b> <b>0900 – 0945 hrs</b>	<p><b>Welcome and Setting the Context</b> Mr Sudarshan Jain, Secretary General - Indian Pharmaceutical Alliance</p> <p><b>Inaugural Address</b> Mr Satish Reddy, President - Indian Pharmaceutical Alliance</p> <p><b>Keynote Address</b> Dr P D Vaghela, Secretary - Department of Pharmaceutical, GoI</p> <p><b>Release of IPA Guidelines on Market Complaints</b> McKinsey &amp; Co. and Quality Subgroup</p>
<b>Session 2</b> <b>0945-1045 hrs</b>	<p><b>Global View of Regulatory Affairs</b> <b>Message from Dr Janet Woodcock, USFDA</b> <i>Moderator:</i> Mr Shirish Belapure, Senior Technical Advisor – Indian Pharmaceutical Alliance Dr V G Somani, DCG(I) Mr Declan Byrne, Scientific Officer, Certification of Substances Division, EDQM Dr Samantha Atkinson, Director of Inspection, Enforcement and Standards (IE &amp;S), MHRA Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO (West)</p>
<b>1045-1100 hrs</b>	<b>Networking Tea/Coffee</b>
<b>Session 3</b> <b>1100-1200 hrs</b>	<p><b>Quality &amp; Patient Centricity</b> <i>Moderator:</i> Mr Vikas Bhadoria, Senior Partner – McKinsey &amp; Co. Dr Y K Gupta, President, AIIMS Bhopal Mr Jeff Francer, Interim CEO and General Counsel - AAM Dr B Suresh, President PCI</p>
<b>Session 4</b> <b>1200-1245 hrs</b>	<p><b>CDER/OC/OMQ Update and Recent Cross Contamination Case Studies</b> Dr Francis Godwin, Director, Office of Manufacturing Quality, Office of Compliance, USFDA Q&amp;A</p>
<b>1245-1330 hrs</b>	<p><b>Surveillance Inspections and Recent Trends</b> Mr Jay Jariwala, Assistant Country Director (Drugs), USFDA (India) Q&amp;A</p>
<b>1330-1430 hrs</b>	<b>Networking Lunch</b>
<b>Session 5</b> <b>1430-1545 hrs</b>	<p><b>Quality by Design for Robust Product</b> Dr James Pound, Group Manager British Pharmacopeia and Laboratory Services, MHRA Mr Vipul Doshi, President-Corporate Quality, Cadila Healthcare Q&amp;A</p>
<b>1545-1615 hrs</b>	<b>Networking Tea/Coffee</b>
<b>Session 6</b> <b>1615-1800 hrs</b>	<p><b>Culture Transformation Best Practices</b> Dr Samantha Atkinson, Director of Inspection, Enforcement and Standards (IE &amp;S), MHRA Ms Susan Schniepp, Chair-Elect, PDA Experience sharing by Mr Johnny Mikell, President – Global Quality and Compliance, Lupin Q&amp;A</p>
<b>1930-2300hrs</b>	<b>Cocktail Reception &amp; Dinner - All Participants</b>

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#### Day 2: 28 February 2020

<p><b>Session 7</b> <b>0900-1000hrs</b></p> <p><b>1000-1100 hrs</b></p>	<p><b>Commitment to Quality in Pharmaceutical Development and Commercial Manufacturing</b> Dr Stelios Tsinontides, Director, Office of Process and Manufacturing Assessment, USFDA Q&amp;A</p> <p><b>Cost of Quality</b> Dr Ranjana Pathak, President - Global Quality Medical Affairs &amp; Pharmacovigilance, Cipla Q&amp;A</p>
<p><b>1100-1130hrs</b></p>	<p><b>Networking Tea/Coffee</b></p>
<p><b>Session 8</b> <b>1130-1215hrs</b></p> <p><b>1215-1300hrs</b></p>	<p><b>Digital Technologies in Pharma Operation for Improved Quality</b> Matthias Spiegl, Associate Partner – McKinsey &amp; Co. Q&amp;A</p> <p><b>Global Best Practices in Capability Building</b> Mr Jaidev Rajpal, Partner – McKinsey &amp; Co. Q&amp;A</p>
<p><b>1300-1400hrs</b></p>	<p><b>Networking Lunch</b></p>
<p><b>Session 9</b> <b>1400-1515hrs</b></p>	<p><b>Nitrosamine Impurities – Current Status &amp; Expectations</b> Dr Declan Byrne, Scientific Officer, Certification of Substances Division, EDQM Dr Milind Joshi, President – Global Regulatory Management, JB Chemicals Q&amp;A</p>
<p><b>1515-1545hrs</b></p>	<p><b>Networking Tea/Coffee</b></p>
<p><b>Session 10</b> <b>1545-1730hrs</b></p>	<p><b>CEO Panel: Patient Centricity and Integrated Quality Management</b> <i>Moderator:</i> Mr Gautam Kumra, Managing Partner - McKinsey &amp; Co. <i>Panellists:</i> 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 Ms Samina Hamied, Executive Vice Chairperson - Cipla Ltd Q&amp;A</p>
<p><b>1730-1745hrs</b></p>	<p><b>Closing Remarks</b> Mr Nilesh Gupta, Chair Quality Forum - Indian Pharmaceutical Alliance</p>

\* Subject to change without prior notice.