

**India Pharmaceutical Forum 2018**  
**Day-1: 22 February 2018 - Pre-Conference Workshops**

Session No.	Timing	Batch Failure Investigation & Data Integrity		Complaints – Investigation and Review - USFDA/EMA		Good Documentation Practice - MHRA	
		Topic	Speakers	Topic	Speakers	Topic	Speakers
1	0900 – 0910 hrs	Welcome and Opening Remarks	IPA	Welcome and Opening Remarks	IPA	Welcome and Opening Remarks	IPA
	0910 – 0945 hrs	Setting the Context	Mr Vivek Arora McKinsey & Co	Setting the Context	Dr Jaidev Rajpal McKinsey & Co	Setting the Context	Mr Kartik Reddy McKinsey & Co
	0945 – 1030 hrs	Presentation by the IPA Sub-group - 4	Mr Pradeep Chakravarty Lupin	Presentation by the IPA Sub-group - 5	Mr Avinash Joshi Cadila Healthcare	Presentation by the IPA Sub-group - 6	Mr Sanjay Shetgar Dr Reddys Lab
2	1030 - 1115 hrs	Data Quality and Integrity - 1	Mr Howard Sklamberg Akin Gump	How to Proceed – Essential Parameters	Dr Ademola Daramola India Office, USFDA	Practical Steps to Good Documentation	Mr Gerald Heddell, MHRA Or Mr Mark Birse, MHRA
	<b>1115 - 1130 hrs</b>	<b><i>Networking Tea/Coffee</i></b>					
3	1130 - 1215 hrs	Data Quality and Integrity - 2	Mr Howard Sklamberg Akin Gump	Root Cause Analysis	Dr Ademola Daramola India Office, USFDA	How to Ensure Good Documentation Practice	Mr Gerald Heddell, MHRA Or Mr Mark Birse, MHRA
4	1215 - 1300 hrs	Data Quality and Integrity - 3	Mr Howard Sklamberg Akin Gump	Remediation, Resolution and Outcomes	Mr Andrei Spinei EMA	Consequences of Poor Documentation	Mr Gerald Heddell, MHRA Or Mr Mark Birse, MHRA
	<b>1300 - 1400 hrs</b>	<b><i>Networking Lunch</i></b>					
5	1400 - 1530 hrs	Case Study	TBA	Case Study	Dr Ademola Daramola India Office, USFDA	Case Study	Mr Gerald Heddell, MHRA Or Mr Mark Birse, MHRA
	<b>1530 - 1600 hrs</b>	<b><i>Networking Tea/Coffee</i></b>					
6	1600 - 1730 hrs	General Question and Answer Session	All Panellists	General Question and Answer Session	All Panellists	General Question and Answer Session	All Panellists
	<b>1930 - 2300 hrs</b>	<b><i>Cocktail Reception &amp; Dinner - All Participants</i></b>					

**India Pharmaceutical Forum 2018**  
**Day-2: 23 February 2018 - Conference**

<b>0800hrs Onwards</b>	<b>Registration and Networking</b>	
<b>Session 1</b> <b>0900 - 1000 hrs</b>	<b>Inaugural Address</b> President, Indian Pharmaceutical Alliance <b>Opening Remarks</b> USFDA India Office Representative, MHRA Representative, EMA Representative, CDSCO <b>The Conference Agenda and Setup</b> Mr Dilip G Shah - Secretary General, Indian Pharmaceutical Alliance	0900 – 0910  0910 – 0950  0950 – 1000
<b>Session 2</b> <b>1000 - 1115 hrs</b>	<b>Reflections on Journey So Far</b> Mr Vikas Bhadoria, Senior Partner, McKinsey & Co. <b>Release of IPA Process Validation Guideline</b> <b>Release of IPA Good Documentation Practice Guideline</b> Dr R K Vats, Additional Secretary, MoH&FW <b>Report Highlights</b> Mr Vivek Arora, Associate Partner, McKinsey & Co Dr Jaidev Rajpal, Partner, McKinsey & Co.	1000 – 1025  1025 – 1045  1045 – 1100 1100 - 1115
<b>1115 - 1130 hrs</b>	<b>Networking Tea/Coffee</b>	<b>1115 – 1130</b>
<b>Session 3</b> <b>1130 - 1215 hrs</b>	<b>Driving Sustainable Cultural Transformation</b> Mr Gerald Heddell, Director Inspection, Enforcement & Standards, MHRA Mr Andrei Spinei, Scientific Administrator, EMA Panel for Q&A	1130 – 1145  1145 – 1200 1200 – 1215
<b>Session 4</b> <b>1215 - 1300 hrs</b>	<b>Building Integrated Capabilities for Quality Excellence</b> Mr David Keeling, Senior Partner, McKinsey & Co. Mr Bart Janssens, Partner & Director, BCG Panel for Q&A	1215 – 1230 1230 – 1245 1245 – 1300
<b>1300 - 1400 hrs</b>	<b>Networking Lunch</b>	<b>1300 – 1400</b>
<b>Session 5</b> <b>1400 - 1500 hrs</b>	<b>Building Quality Metrics</b> Mr Howard Sklamberg, Partner, Akin Gump Mr Mark Birse, Group Manager Inspectorate, MHRA Dr Ademola Daramola, Assistant Country Director - India Office, USFDA Panel for Q&A	1400 – 1415 1415 – 1430 1430 – 1445 1445 –1500
<b>Session 6</b> <b>1500 – 1530 hrs</b>	<b>Electronic Documentation</b> Mr Mark Birse, Group Manager Inspectorate, MHRA Panel for Q&A	1500 – 1515 1515 – 1530
<b>1530 - 1600 hrs</b>	<b>Networking Tea/Coffee</b>	<b>1530 – 1600</b>
<b>Session 7</b> <b>1600 - 1745 hrs</b>	<b>CEO Forum: Way Forward</b> <b>Moderator:</b> Mr David Keeling, Senior Partner, McKinsey & Co. <b>Panellists:</b> 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 Sharvil Patel, Managing Director - Cadila Healthcare Ltd Mr Umang Vohra, Managing Director and CEO - Cipla Ltd Mr Samir Mehta, Chairman - Torrent Pharmaceuticals Ltd Q&A	1600 – 1730          1730 – 1745
<b>1745 – 1800 hrs</b>	<b>Closing Remarks:</b> Mr Dilip G Shah – Secretary General, IPA	1745 – 1800