

Advanced GMP Workshops 2018
AGENDA*

Day 1

0900hrs Onwards	Registration and Networking
Session 1 0930 - 1015 hrs	<p>Inaugural Session – <i>Setting the Context</i></p> <p>Dr S Eswara Reddy, Drugs Controller General (India), CDSCO Dr Letitia Robinson, Director, USFDA India Office Mr Vimal Sachdeva, Technical Officer (Senior Inspector), WHO Mr Ewan Norton, Senior GMDP Inspector, MHRA Mr D G Shah, Secretary General, IPA</p>
1015 - 1045 hrs	Networking Tea/Coffee
Session 2 1045 - 1200 hrs	<p>Key Trends in Quality and GMP Inspections</p> <p>Mr Thomas Arista, Deputy Director, USFDA India Office</p> <p>Q&A</p>
Session 3 1200 - 1315 hrs	<p>Quality Metrics with Case Study</p> <p>Goa Mr Vivek Arora, Associate Partner, McKinsey & Company Mr Indrajit Bose, Sr General Manager (CQA), Lupin</p> <p>Hyderabad Dr Jaidev Rajpal, Partner, McKinsey & Company Mr Sairam Philkana, Sr Director (Quality Assurance), Dr Reddy’s Laboratories</p> <p>Ahmedabad Mr Vivek Arora, Associate Partner, McKinsey & Company Dr Ranjana Pathak, Global Head (Quality), Cipla</p> <p>Q&A</p>
1315 - 1415 hrs	Lunch
Session 4 1415 - 1530 hrs	<p>Good Data and Record Management Practices - <i>Sharing of Experiences & Issues</i></p> <p>Mr Vimal Sachdeva, Technical Officer (Senior Inspector), WHO</p> <p>Q&A</p>
1530 - 1545 hrs	Networking Tea/Coffee
Session 5 1545 - 1700 hrs	<p>Organization Culture – <i>Expectations of a Regulator</i></p> <p>Mr Ewan Norton, Senior GMDP Inspector, MHRA</p> <p>Q&A</p>

Day 2

<p>Session 6 0930 - 1000 hrs</p>	<p>Recap of Day 1</p>
<p>Session 7 1000 - 1115 hrs</p>	<p>FDA Inspection Process - <i>What You Should Anticipate</i></p> <p>Mr Robert Iser, Former Director, Office of Process and Facilities CDER, USFDA & Vice President, PAREXEL Consulting</p> <p>Q&A</p>
<p>1115 - 1145 hrs</p>	<p><i>Networking Tea/Coffee</i></p>
<p>Session 8 1145 - 1300 hrs</p>	<p>Building Quality Culture & Capabilities</p> <p>Goa Dr Jaidev Rajpal, Partner, McKinsey & Company Mr Prashant Sharma, President (Group Formulations, Mfg & Operations), Zydus Cadila</p> <p>Hyderabad Mr Vivek Arora, Associate Partner, McKinsey & Company Mr Jiwan Goyal, Associate Director (Operations Excellence & Culture Transformation), Dr Reddy's Laboratories</p> <p>Ahmedabad Mr Vivek Arora, Associate Partner, McKinsey & Company Mr Vipul Doshi, President (Corporate Quality), Cadila Healthcare</p> <p>Q&A</p>
<p>1300 - 1400 hrs</p>	<p><i>Lunch</i></p>
<p>Session 9 1400 - 1515 hrs</p>	<p>Next Gen Quality - Impact of Digital & Advanced Analytics on Quality</p> <p>Mr Daniele Iacovelli, Expert Associate Partner, McKinsey & Company, Germany Mrs Julie Rose, Expert Associate Partner, McKinsey & Company, France</p> <p>Q&A</p>
<p>1515 - 1545 hrs</p>	<p><i>Networking Tea/Coffee</i></p>
<p>Session 10 1545 - 1645 hrs</p>	<p>CxO Panel Discussion and Q& A</p>

*Subject to change without prior notice.