

Advanced GMP Workshops 2019
AHMEDABAD (14-15 November 2019)

AGENDA*

Day 1

0830hrs Onwards	Registration and Networking
0930 - 1015 hrs	<p>Inaugural Session – Setting the Context</p> <ul style="list-style-type: none"> • Mr Arvind Kukrety, Deputy Drugs Controller (India) - CDSCO • Dr H G Koshia, FDA Commissioner, Gujarat - FDA • Mr Roberto Conocchia, Scientific Administrator - EMA • Mr Shirish Belapure, Senior Technical Advisor - IPA
1015 - 1045 hrs	Networking Tea/Coffee
Session 1 1045 - 1200 hrs	<p>Recent Trends in Inspection of Sterile Dosage Form</p> <ul style="list-style-type: none"> • Mr Philip E M Crooker, Former Regulatory Counsel - USFDA and Vice President, Technical - Parexel Consulting
Session 2 1200 - 1315 hrs	<p>Pharma Digitalised World-Cyber Security Controls / Role of Artificial Intelligence in Data Monitoring and Data Analytics in Pharma Operations</p> <ul style="list-style-type: none"> • Mr Ayman Al Issa, Lead Industrial Cyber Security, Middle East - McKinsey & Co. • Mr Vishnu Kant Pitty, Engagement Manager – McKinsey & Co.
1315 - 1415 hrs	Networking Lunch
Session 3 1415 - 1500 hrs 1500 - 1545 hrs	<p>Robust Technology Transfer</p> <ul style="list-style-type: none"> • Mr Roberto Conocchia, Scientific Administrator - EMA <p>Validation of Analytical Methods</p> <ul style="list-style-type: none"> • Dr Sharad Mankumare, Director RSL & Verification Programs - USP India
1545 - 1600 hrs	Networking Tea/Coffee
Session 4 1600 - 1700 hrs	<p>Excipients Risk Management: New PDA Technical Report</p> <ul style="list-style-type: none"> • Dr Tina Morris, Vice President, Scientific & Regulatory Affairs – PDA

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Day 2

0930 - 1000 hrs	Recap of Day 1
Session 5 1000 - 1115 hrs	<p>Experience of Transformation of Culture with respect to Quality – Experience Sharing by Companies</p> <ul style="list-style-type: none"> • Mr Vikram Shukla, Vice President - Pfizer
1115 - 1145 hrs	<i>Networking Tea/Coffee</i>
Session 6 1145 - 1300 hrs	<p>CGMPs Aspects of NCE Development for Early Phase INDs - CMC Perspective</p> <ul style="list-style-type: none"> • Dr Balaram Nageswara Rao, Head CMC Regulatory Affairs and Quality - Aurigene
1300 - 1400 hrs	<i>Networking Lunch</i>
Session 7 1400 - 1500 hrs 1500 – 1600 hrs	<p>Data Integrity: New PDA Technical Reports on DI in the Laboratory, Manufacturing, and QMS Systems</p> <ul style="list-style-type: none"> • Dr Tina Morris, Vice President, Scientific & Regulatory Affairs – PDA <p>Continuous Manufacturing – Current Trends</p> <ul style="list-style-type: none"> • Mr Harish Krishnan, Application Manager - GEA
1600 - 1615 hrs	<i>Networking Tea/Coffee Break</i>
Session 8 1615 - 1700 hrs	<p>Panel Discussion and Q&A</p> <p>Learning Reflections & Way Forward</p> <ul style="list-style-type: none"> • Mr Shirish Belapure, Senior Technical Advisor - IPA

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