Advanced GMP Workshops 2019

HYDERABAD (18-19 November 2019)

AGENDA*

Day 1

0830hrs Onwards	**Registration and Networking**
0930 - 1015 hrs	**Inaugural Session – Setting the Context** • Dr Annam Visala, Deputy Drugs Controller - CDSCO • Mr Satish Reddy, Chairman - DRL • Mr Sudarshan Jain, Secretary General - IPA • Mr S G Belapure, Senior Technical Advisor - IPA
1015 - 1045 hrs	***Networking Tea/Coffee***
Session 1 **1045 - 1200 hrs**	**Recent Trends in Inspection of Sterile Dosage Form** • Mr Philip E M Crooker, Former Regulatory Counsel - USFDA and Vice President, Technical - Parexel Consulting
Session 2 **1200 - 1315 hrs**	**Data Integrity: New PDA Technical Reports on DI in the Laboratory, Manufacturing, and QMS Systems** • Dr Tina Morris, Vice President, Scientific & Regulatory Affairs - PDA
1315 - 1415 hrs	***Networking Lunch***
Session 3 **1415 - 1500 hrs**	**Leveraging Automation in Pharmaceutical Operations for Continuous Improvement** • Mr Ganadhish Kamat, Global Head of Quality - Dr Reddy's Laboratories
1500-1545 hrs	**Pharma Digitalised World-Cyber Security Controls / Role of Artificial Intelligence in Data Monitoring and Data Analytics in Pharma Operations** • Mr Ayman Al Issa, Lead Industrial Cyber Security, Middle East - McKinsey & Co.
1545 - 1600 hrs	***Networking Tea/Coffee***
Session 4 **1600 - 1700 hrs**	**Continuous Manufacturing – Current Trends** • Mr Harish Krishnan, Application Manager - GEA

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Day 2

0930 - 1000 hrs	**Recap of Day 1**
Session 5 **1000 - 1115 hrs**	**Experience of Transformation of Culture with respect to Quality – Experience Sharing by Companies** • Dr Ranjana Pathak, President, Quality - Cipla
1115 - 1145 hrs	***Networking Tea/Coffee***
Session 6 **1145 - 1300 hrs**	**Excipients Risk Management: New PDA Technical Report** • Dr Tina Morris, Vice President, Scientific & Regulatory Affairs - PDA
1300 - 1400 hrs	***Networking Lunch***
Session 7 **1400 - 1500 hrs** **1500 – 1600 hrs**	**CGMPs Aspects of NCE Development for Early Phase INDs - CMC Perspective** • Dr Balaram Nageswara Rao, Head CMC Regulatory Affairs and Quality - Aurigene **Validation of Analytical Methods** • Dr Sharad Mankumare, Director RSL & Verification Programme - USP India
1600 - 1615 hrs	***Networking Tea/Coffee Break***
Session 8 **1615 - 1700 hrs**	**Panel Discussion and Q&A** **Learning Reflections & Way Forward** • Mr Shirish Belapure, Senior Technical Advisor - IPA

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