

Advanced GMP Workshops 2019
(GOA: 11-12 November 2019)

AGENDA*

Day 1

0830hrs Onwards	Registration and Networking
0930 - 1015 hrs	Inaugural Session – Setting the Context <ul style="list-style-type: none"> • Dr V G Somani, Drugs Controller General (India) - CDSCO • Mr Alonza Cruse, Director, Office of Pharmaceutical Quality Operations – USFDA • Mr Roberto Conocchia, Scientific Administrator - EMA • Dr Rubina Bose, Deputy Drugs Controller (India) - CDSCO (West Zone) • Ms Jyoti Sardesai, Director – FDA, Goa • Mr Sudarshan Jain, Secretary General - IPA
1015 - 1045 hrs	Networking Tea/Coffee
Session 1	Recent Trends in Inspection of Sterile Dosage Form
1045 - 1200 hrs	<ul style="list-style-type: none"> • Mr Alonza Cruse, Director, Office of Pharmaceutical Quality Operations – USFDA • Mr Jay Jariwala, Assistant Country Director (Drugs), India Office - USFDA
1200 – 1315 hrs	<ul style="list-style-type: none"> • Mr Philip E M Crooker, Former Regulatory Counsel - USFDA and Vice President, Technical – Parexel Consulting
1315 - 1415 hrs	Networking Lunch
Session 2	Robust Technology Transfer
1415 - 1500 hrs	<ul style="list-style-type: none"> • Mr Roberto Conocchia, Scientific Administrator - EMA
1500-1545 hrs	Validation of Analytical Methods <ul style="list-style-type: none"> • Dr Sharad Mankumare, Director RSL & Verification Programs - USP India
1545 - 1600 hrs	Networking Tea/Coffee
Session 3	Continuous Manufacturing – Current Trends
1600 - 1700 hrs	<ul style="list-style-type: none"> • Mr Harish Krishnan, Application Manager - GEA

*Subject to change without prior notice

Advanced GMP Workshops 2019
(GOA: 11-12 November 2019)

AGENDA*

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 Sunil Kumar, Director & Global Head, Culture Transformation & Operational Excellence - Cipla
1115 - 1145 hrs	<i>Networking Tea/Coffee</i>
Session 6 1145 - 1300 hrs	<p>QBD in Analytical Development</p> <ul style="list-style-type: none"> Ms Jila Breeze, Senior Vice President, Global Head of Quality & Compliance - Sun Pharma Dr Pradeep Sanghvi, Head R&D - Sun Pharma
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>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.
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

*Subject to change without prior notice