

7th Advanced GMP Workshop 2022

Hyderabad (13 – 14 October 2022)

Agenda

Day 1: 13 October 2022

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| Session 1 1000 – 1045 hrs | Welcome and Setting the Context Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance Inaugural Address Rajeev Nannapaneni – Co-Chair Quality Forum, Indian Pharmaceutical Alliance Opening Address Sarah McMullen – Country Director, India Office, Office of Global Operations, USFDA* Keynote Address A Ramkishan – Deputy Drugs Controller (India), CDSCO |
| Session 2 1045 – 1215 hrs | Cross Contamination control in parenteral and solid orals Thomas Arista – Consumer Safety Officer, Office of Regulatory Affairs, USFDA* Amit Sareen - Senior Vice President, Manufacturing, Lupin |
| 1215 – 1230 hrs | Tea / Coffee Break |
| Session 3 1230 – 1400 hrs | Investigations Best Practices Thomas Hecker – Inspector, Certification of Substances Department, EDQM* Mark Birse – Vice President Technical, Parexel International |
| 1400 – 1500 hrs | Lunch Break |
| Session 4 1500 – 1630 hrs | Current Trends in Media Fill Ivy Louis – Member, Science Advisory Board, PDA Inc. Sanjay Jain – President, Amneal Pharmaceuticals |
| 1630 – 1645 hrs | Tea / Coffee Break |
| Session 5 1645 – 1815 hrs | Data Integrity - Crux of the Trust Jay Jariwala - Sr. Director, Reg. Compliance, Sidley Austin LLP Mr Jose Hernandez – Principal and Owner, 5WS Consulting |
| Session 6 1815 – 1900 hrs | Process deficiencies for ANDAs – a dive into trends Vidya Pai - Branch Chief, Office of Pharmaceutical Manufacturing Assessment, Office of Pharmaceutical Quality, USFDA* |
| Session 8 1900 – 1930 hrs | IPA Quality Forum Subgroups: Nitrosamine and other ICH M7 impurities B M Rao – Partner and CEO, QDot Associates |

*Speakers will join virtually

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Day 2: 14 October 2022

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| Session 6 1000 – 1130 hrs | Implementation of PAT in Solid Orals Gautam Samanta – Vice President, Head-Quality by Design, Scale-up, Tech Transfer, Cipla Process Safety in Pharmaceutical Industry Rajender Kumar - Senior Director, Synthetics Dept, USP India |
| 1130 – 1145 hrs | Tea / Coffee Break |
| Session 7 1145 – 1315 hrs | Advancements in Isolator Technology Julien Cabon – Business Development Manager - Asia Pacific, Ecolab Shraavan Kumar Malisetty - Head Of Quality Sterile, Dr Reddy's Laboratories |
| 1315 – 1415 hrs | Lunch Break |
| Session 8 1415 – 1615 hrs | IPA Quality Forum Subgroups <ul style="list-style-type: none"> • Digital Data Management – CFR Part 11 Compliance Rajesh Thempadiyil - Head – Quality Digital Transformation Digital & Process Excellence Dr. Reddy's Laboratories • Human Error Reduction Nilanjana Basu - Senior General Manager, Technical Training and Operational Excellence, Lupin • Technology transfer – Dosage forms Ashish Parekh – Vice President, MSTG, Sun Pharma |
| 1615 – 1630 hrs | Tea / Coffee Break |
| Session 9 1630 – 1800 hrs | Panel Discussion: Advancements in Environmental Monitoring Moderator: Rajiv Desai - Senior Technical Advisor, Indian Pharmaceutical Alliance Thomas Hecker – Inspector, Certification of Substances Department, EDQM* Vishal Sharma – President, PDA India Chapter Bhavesh Shah - Vice President, Quality, Zydus Lifesciences* |
| Session 10 1800 – 1815 hrs | Vote of Thanks Rajiv Desai - Senior Technical Advisor, Indian Pharmaceutical Alliance |

*Speakers will join virtually