Address: A-205, Sangam Building 14B, S V Road, Santacruz West, Mumbai 400 054, India. | **O:** +91 22 2610 9281 | **F:** +91 22 2610 9282

7th Advanced GMP Workshop 2022

Goa (17 – 18 October 2022)

Agenda

Day 1: 17 October 2022

Session 1 **1000 – 1045 hrs**	**Welcome and Setting the Context** Shirish Belapure – Senior Technical Advisor, Indian Pharmaceutical Alliance **Inaugural Address** Jyoti Sardesai – Director, Food and Drugs Administration, Goa **Opening Address** Sarah McMullen – Country Director, India Office, Office of Global Operations, USFDA
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*

*Speakers will join virtually

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Day 2: 18 October 2022

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** P S Tang – Regional Service Manager, Asia-Pacific, Ecolab Shravan Kumar Malisetty - Head Of Quality Sterile, Dr Reddy's Laboratories
1315 – 1415 hrs	**Lunch Break**
Session 8 **1415 – 1615 hrs**	**IPA Quality Forum Subgroups** • **Digital Data Management – CFR Part 11 Compliance** Rajeev Bedage - Head-Manufacturing-IT, CSV & IT Compliance, Lupin • **Nitrosamine and other ICH M7 impurities** B M Rao – Partner and CEO, QDot Associates • **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 Madhur Gupta – Technical Officer - Pharmaceuticals, World Health Organization, Country Office for India 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