### 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 |
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| Session 3 | 1230 – 1400 hrs | Investigations Best Practices  
Thomas Becker – Inspector, Certification of Substances Department, EDQM*  
Mark Birse – Vice President Technical, Parexel International |
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| Session 4 | 1500 – 1630 hrs | Current Trends in Media Fill  
Ivy Louis – Member, Science Advisory Board, PDA Inc.  
Sanjay Jain – President, Amneal Pharmaceuticals |
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| 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, SWS Consulting |
|------------|----------------|--------------------------------------------------------------------------------|
|            |                | **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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| 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 |
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<td><strong>1130 – 1145 hrs</strong></td>
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| **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*