PharmaLytica 2023

01st – 02nd June 2023, HITEX International Convention & Exhibition Center, Hyderabad, India

AGENDA AT A GLANCE:

Day 1	Day 2
• CMO • API • Excipients • Manufacturing • Partnerships • Development & Validation • Lab & Analytical • Telangana Life Sciences	• Supply Chain • OSD • Digitalisation • Quality & Risk Management • RWE & RWD • Packaging, Labelling, Serialization, Track & Trace • Roadmap to 2024

Day 1 – 01st June 2023

Time	Topic	Panelists/ Speakers
10:00	**Welcome Address & Conference Inauguration**	
	CONTRACT MANUFACTURING	
11.00	**Keynote Panel Discussion –** **Why the pharmaceutical industry is turning to outsourced manufacturing?** • Collaborating with partners that meet your business needs • Points to be considered by pharma and bio-techs when choosing the right CMO • Assessing if your current partnerships are effective in achieving the desired output and standards	**Moderator:** **VISHWAS SOVANI,** Director, **Pharma Wisdom** **Panelists:** **SUDEEP SRIVASTAVA,** Senior Vice President, **Biological E. Limited**

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	• Understanding the needs, culture and relationship required to partner successfully with CMOs • Creating improvement opportunities with CMOs • Creating a win-win approach • Flexibility in operations and contractual agreements that don't constrain development	**SATYA BABU,** Sr. VP and Head - Operations, Quality, Regulatory and Scientific Affairs, **Biological E. Limited** **VIMAL KOTHARI,** Associate Director - External Manufacturing, **Dr. Reddy's Laboratories** **ANISH AGARWAL,** Global Head of Analytics, **Dr. Reddy's Laboratories** **PRAVEEN CHERUKUPALLI,** Senior Vice President & Head-API R&D**, Innovare Labs**
	SOLAR PV	
12:00	**Presentation –** **Solar PV Adoption for Pharmaceutical Industry for their operational cost savings and sustainability goals** • Rooftop & Ground mount Solar PV solution suitability • OPEX, CAPEX & Open Access mode of Solar PV adoption • Case Study of Solar Adoption for a Pharmaceutical client	**Speaker** **YOGISH HN,** AVP – Business Development, **Enerparc Energy**
12:30	**Lunch Break & Networking**	
	API	
13:30	**Panel Discussion –** **Latest developments and trends in the Pharma API industry**	**Moderator:** **VISHWAS SOVANI,** Director, **Pharma Wisdom**

	• How to reduce API manufacturing costs and get the best value for your money without cutting back on the importance of safety and containment procedures. • Importance of proper communication - Information sharing between the API manufacturer and the Drug Product manufacturer • Increasing trend toward more potent therapies and the consequences of the changing face of pharma • Comply - Must have QR code in each packing of API and medicine • Regulatory hurdles and opportunities	**Panelists:** **NASIR ALI,** Associate Vice President - API R&D, **Aurobindo Pharma** **KRISHNA BHAVANASI,** VP Head Formulation R&D, **Natco Pharma** **NARENDER RAO SOMISETTI,** Vice President, Head-R & D, **Metrochem API** **SRINIVASA RAO SAMBANGI,** Sr. General Manager, **Aurobindo Pharma** **RAJNI JHA,** IIT Kanpur Scholar Synthetic Organic Chemistry, Trainer for QBD, GMP n Regulatory Affairs & **(**Former Head Of Regulatory Affairs, **Naari Pharma)**
NITROSAMINE		
14:30	**Presentation –** **Nitrosamine Impurities in Pharmaceuticals**	**Speaker** **PRAVEEN CHERUKUPALLI,** Senior Vice President & Head-API R&D**, Innovare Labs**
15:00	**Coffee Break**	
ANALYTICAL PROCEDURES – DEVELOPMENT & VALIDATION		

15:30	**Presentation –** **Scientific approaches to analytical procedure development** • Guidance to the analytical procedure development and validation of developed methods • Method performance through system suitability testing - future expectations from USP<621> • Practical challenges and suggested solutions • Key validation parameters that characterise analytical procedures • Use of analytical testing to support pharmaceutical quality systems • Discussion of analytical lifecycle management	**Speaker** **BM RAO,** CEO **- QDOT Associates**
	LAB & ANALYTICAL	
16:00	**Keynote Panel Discussion –** **Pioneering laboratory knowledge - Future of Lab** • Quality management in the laboratory • Sustainability in the laboratory / Lab automation / Lab and tech integration • Future-proofing labs through smart technology and innovation • Future of lab is digitalisation, automation and connectivity: Challenges & tools to engage staff • IoT in the Lab of medicinal Chemistry and the simultaneous impact of AI • Identify out-of-the-box systems and solutions • Review outdated processes, workflows, and tools • Safety and its journey towards improvement	**Moderator:** **PAWAN PATINGE,** Founder, **Academy of Analytical Instrumentation** **Panelists:** **SRINIVAS ACHANTA,** VP, **Dr. Reddy's Laboratories** **GNANADEV GUDIPATI,** Vice President ARD & QC **Natco Pharma** **BALARAM PATRO,** CEO, **GRK Research Laboratories**

		RAJESH THEMPADIYIL, Head – Quality Digital Transformation & Compliance, **Dr. Reddy's Laboratories**
17:00	**End of Day 01**	

Day 2 – 02nd June 2023

Time	**Topic**	**Panelist/ Speakers**
10:00	**Welcome Address & Conference Inauguration**	
	PHARMA SUPPLY CHAIN	
11:00	**Keynote Panel Discussion –** **Latest trends and developments in your supply chain – Moving up the value chain** • Innovative strategies implemented from small-midsize pharma to overcome supply chain issues without incurring significant costs • Pragmatic solutions for overcoming supply chain hurdles • Transportation and logistics issues - where are we heading with this problem? • Common pitfalls in SCM - What are the lookout for facts? • How to insulate your risks against supply disruption • Steps needed to insure supply chain integrity from the raw material stage through the end user • Role of CFAs in in supply chain operation for effective drug supply / distribution to trade	**Moderator:** **VISHWAS SOVANI,** Director, **Pharma Wisdom** **Panelists:** **P V Raju,** Senior Vice President Supply Chain, **Biological E. Limited** **KAMARAJ ABRAHAM,** Associate Vice President, Head Quality Assurance, **Aurobindo Pharma** **APPAJI VENKAT PADMANABHUNI,** Advisor**, BDMA (**Former Policy Advisor, **Pharmexcil)** **MANJEETH SINGH RAWAT,** Head of Pharma Supply Chain

		- CIS & Romania, **Dr. Reddy's Laboratories** **HIMAL P. DESAI,** Vice President, Supply Chain Management, **Virchow Biotech** **LAKSHMI NARAYANA,** Associate Director, SCM, **Aragen**
OSD CONTRACT MANUFACTURING		
12:00	**Presentation –** **The Benefits of Expanding OSD Capacity** • Niche manufacturing trends and techniques • Expectations when working with partners • Cost and price in manufacturing • Continued Development of Integrated Offerings • Safety aspects • Reality VS Expectations	
12:30	**Lunch Break & Networking**	
DIGITALISATION		
13:30	**Panel Discussion –** **Reshaping Pharma industry in the way of digital transformation** • Looking Beyond Pharma 4.0: Future Initiatives and Advanced Manufacturing Approaches • What's New? Innovation in Pharma Industry • Ensure the success of Technology Transfer • Addressing main challenges in implementing digitization in pharma	**Moderator:** **RITHESH P,** Director, Leading Technology Acceleration (Digital Solutions), **Novartis** **Panelists:** **DILIP KASTALA,** VP & Global Head - Digital, IT & Process

	• Making Big Data useful: Practical approaches • How is AI resolving the tech problems faced by the industry? How will the near future be? • Do digital trends really help in manufacturing? How? • Increasing Agility through Digitalization • Technological Evolution in Drug Manufacturing & Drug Delivery	Excellence, **Dr. Reddy's Laboratories** **RAM KUMAR,** Director MSTG, **Cipla** **KAVITA LAMROR,** Expert, Real World Investigator & RWD Product Owner, **Sanofi** **NARENDIRA KUMAR,** Senior General Manger (Quality) | Site Quality Head, **Viatris**
QUALITY & RISK		
14:30	**Presentation –** **Quality culture excellence** • To transform from "Compliance led" to "excellence led". • Guidance and tools for cultural assessment • Few QMS elements as Quality Culture enablers	**Speaker** **NARENDIRA KUMAR,** Senior General Manger (Quality) | Site Quality Head, **Viatris**
15:00	**Coffee Break**	
RWD & RWE		
15:30	**Presentation –** **RWD & RWE - Creating value from next-generation real-world evidence** • How Pharma will handle complexity of data in RWD? • Discussing how the RWE helps to get custom-made treatments and drug therapies for patients • What helps us to have a better understanding about data quality and data privacy? • RWE gives efficient and cost-effective clinical trials? How?	**Speaker** **KAVITA LAMROR,** Expert, Real World Investigator & RWD Product Owner, **Sanofi**

	• What are complications will rise by inserting new data source? And it leads to breakup in data? • Obtaining patient-centric using RWE • What kind of changes needed to be place in RWE? • Compelling with regulatory • Market access for innovative medicines in emerging markets	
	ROADMAP TO 2024	
16:10	**Panel Discussion –** **Future in Manufacturing – Roadmap to 2024 – Moving forward** • Lessons learnt from Covid times – Making the best from the worst times. • Relationships with partners – How should this look by 2024 • Overcoming challenges – Increasing costs and competition • RWD and RWE drive in Pharma • Electronic Quality Management System:- The Role of Modern software like Trackwise, EDMS, LIMS, LMS, e-BMR etc., in pharmaceutical industry and challenges facing during regulatory Audits. • USFDA focus on Recent Quality Management maturity program, Review of Quality metrics data and role of Electronic Quality Management System • Overcoming regulatory constraints	**Moderator:** **SANDHYA PITTALA,** Founder and COO, **Crenza Pharmaceuticals** **Panelists:** **RAJENDAR BURKI,** Associate Vice President, (R&D), **Biological E. Limited** **K. SURESH BABU,** Vice President- Quality Assurance, **NATCO Pharma** **RAHUL MITTAL,** Head Strategy - Emerging Markets, **Dr. Reddy's Laboratories** **VIVEK JHA,** Head - Strategy and Operations, Global Drug Development -India, **Novartis**
17:10	**Break**	

PACKAGING, LABELLING, SERIALISATION, TRACK & TRACE		
18:30	**Panel Discussion –** **PPLST – Pharma Packaging Labelling Serialisation Track & Trace – Where are we heading? Which way is the right direction to improve?** • Preparing for the future of pharma packaging • Fightback against counterfeit online medicine suppliers – How does the packaging help? • How packaging requirements for pharmaceuticals are changing in post pandemic? • Maintaining quality, traceability and accessibility in labeling. • Recent trends in serialization track and trace • New and major problems in implementing trace and trace in supply chain • Ensuring end to end supply chain in pharma – How the serialization helps maintaining dignity of products	**Moderator:** **SANDHYA PITTALA,** Founder and COO, **Crenza Pharmaceuticals** **Panelists:** **GUNJAN SINGH**, VP and Head Mature Markets API (US, EU, Mexico, Canada, CIS), **Dr. Reddy's Laboratories** **VINAY SINGH,** Associate director – Supply Chain Management, **Dr. Reddy's Laboratories** **CHANDI PRASAD RAVIPATI,** Head - Packaging Development, **Aurobindo Pharma** **LOKESH PATEL,** Founder Director, **URL Aseptic Automation** **SUNIL CHANDUPATLA,** AGM, Labelling, COE, **Freyr Solutions**
19:30	**Networking Cocktail Dinner**	