

PharmaLytica 2023

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

AGENDA AT A GLANCE:

Day 1	Day 2
<ul style="list-style-type: none"> • CMO • API • Excipients • Manufacturing • Partnerships • Development & Validation • Lab & Analytical • Telangana Life Sciences 	<ul style="list-style-type: none"> • 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	
<i>CONTRACT MANUFACTURING</i>		
11.00	Keynote Panel Discussion – Why the pharmaceutical industry is turning to outsourced manufacturing? <ul style="list-style-type: none"> • 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:

	<ul style="list-style-type: none"> • 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 	<p>SUDEEP SRIVASTAVA, Senior Vice President, Biological E. Limited</p> <p>PRASAD S. DESHPANDE, SVP Global Head of Procurement, Supply Chain, Contract Manufacturing & Central Engineering, Biocon</p> <p>SATYA BABU, Sr. VP and Head - Operations, Quality, Regulatory and Scientific Affairs, Biological E. Limited</p> <p>VIVEK M K DUBEY, Associate Director PHAD PDU Oral Novartis Heat, Novartis</p> <p>RAJKUMAR RAJAGOPAL, Head, Fermentation Technology Development Centre (FTDC), Dr. Reddy's Laboratories</p> <p>ANISH AGARWAL, Global Head of Analytics, Dr. Reddy's Laboratories</p>
<i>CMO RELATIONSHIP</i>		
12:00	<p>Presentation – Fundamentals of a strong CMO (contract manufacturing organizations) relationship?</p> <ul style="list-style-type: none"> • Importance of consistent communication with partners • Maintaining a high service level across a broad portfolio • Optimizing the CMO selection and management process 	

	<ul style="list-style-type: none"> • Understanding best practices and applying them across the network • Making sure you have the right partner at the right time • Getting service and priority with small volumes or during volume reduction 	
12:30	Lunch Break & Networking	
<i>API</i>		
13:30	<p>Panel Discussion – Latest developments and trends in the Pharma API industry</p> <ul style="list-style-type: none"> • 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 	<p>Moderator:</p> <p>VISHWAS SOVANI, Director, Pharma Wisdom</p> <p>Panelists:</p> <p>DEEPAK SAPRA, Director, Aurigene Pharma (CEO (API & Services) Dr. Reddy's Laboratories)</p> <p>NASIR ALI, Associate Vice President - API R&D, Aurobindo Pharma</p> <p>KRISHNA BHAVANASI, VP Head Formulation R&D, Natco Pharma</p> <p>NARENDER RAO SOMISETTI, Vice President, Head-R & D, Metrochem API</p> <p>TAUSIF AHMED, Head - Biopharmaceutics, Preclin & Clinical Bioanal, Global Clinical</p>

		<p>Management (VP), Dr. Reddy's Laboratories</p> <p>SRINIVASA RAO SAMBANGI, Sr. General Manager, Aurobindo Pharma</p>
<i>TELANGANA LIFE SCIENCES</i>		
14:30	<p>Presentation – Telangana Life Sciences - Overview of the Life Sciences sector in the state of Telangana</p> <p>With a focused approach in incentivising investments, the Life Sciences sector in Telangana has received over INR 25,0000 Crores investments creating over 1.3 Lakh jobs and 4 Lakh indirect jobs. Some of the initiatives like dedicated industrial parks , personalised incentive schemes for corporates, skilling and training programs and BioAsia - Asia's biggest life sciences forum have helped Telangana Life Sciences position Telangana as the "Hub of Life Sciences in Asia".</p>	<p>Speaker</p> <p>SHAKTHI NAGAPPAN, Director (Life Sciences & Pharma) & CEO, Telangana Life Sciences</p>
15:00	Coffee Break	
<i>ANALYTICAL PROCEDURES – DEVELOPMENT & VALIDATION</i>		
15:30	<p>Presentation – Scientific approaches to analytical procedure development</p> <ul style="list-style-type: none"> • 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 	<p>Speaker</p> <p>BM RAO, CEO - QDOT Associates</p>

	<ul style="list-style-type: none"> • Key validation parameters that characterise analytical procedures • Use of analytical testing to support pharmaceutical quality systems • Discussion of analytical lifecycle management 	
<i>LAB & ANALYTICAL</i>		
16:00	<p>Keynote Panel Discussion – Pioneering laboratory knowledge - Future of Lab</p> <ul style="list-style-type: none"> • 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 	<p>Moderator:</p> <p>PAWAN PATINGE, Founder, Academy of Analytical Instrumentation</p> <p>Panelists:</p> <p>RAKESHWAR BANDICHHOR, Head, Chemistry - API - Process R&D, Dr. Reddy's Laboratories</p> <p>GNANADEV GUDIPATI, Vice President ARD & QC Natco Pharma</p> <p>BALARAM PATRO, CEO, GRK Research Laboratories</p> <p>RAJESH THEMPADIYIL, Head – Quality Digital Transformation & Compliance, Dr. Reddy's Laboratories</p>
17:00	End of Day 01	

Day 2 – 02nd June 2023

Time	Topic	Panelist/ Speakers
10:00	Welcome Address & Conference Inauguration	
<i>PHARMA SUPPLY CHAIN</i>		
11:00	<p>Keynote Panel Discussion – Latest trends and developments in your supply chain – Moving up the value chain</p> <ul style="list-style-type: none"> • 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 	<p>Moderator:</p> <p>VISHWAS SOVANI, Director, Pharma Wisdom</p> <p>Panelists:</p> <p>P V Raju, Senior Vice President Supply Chain, Biological E. Limited</p> <p>KAMARAJ ABRAHAM, Associate Vice President, Head Quality Assurance, Aurobindo Pharma</p> <p>APPAJI VENKAT PADMANABHUNI, Policy Advisor, Pharmexcil</p> <p>RIJU VERMA, Country Manager- API & Strategic Procurement, Hikma Pharmaceuticals</p> <p>MANJEETH SINGH RAWAT, Head of Pharma Supply Chain - CIS & Romania, Dr. Reddy's Laboratories</p> <p>HIMAL P. DESAI, Vice President, Supply Chain</p>

		<p>Management, Virchow Biotech</p> <p>LAKSHMI NARAYANA, Associate Director, SCM, Aragen</p>
<i>OSD CONTRACT MANUFACTURING</i>		
12:00	<p>Presentation – The Benefits of Expanding OSD Capacity</p> <ul style="list-style-type: none"> • 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	<p>Presentation – Topic TBC</p>	Speaker TBC
13:00	Lunch Break & Networking	
<i>DIGITALISATION</i>		
14:00	<p>Panel Discussion – Reshaping Pharma industry in the way of digital transformation</p> <ul style="list-style-type: none"> • 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 	<p>Moderator:</p> <p>RITESH P, Director, Leading Technology Acceleration (Digital Solutions), Novartis</p> <p>Panelists:</p> <p>DILIP KASTALA, VP & Global Head - Digital, IT & Process</p>

	<ul style="list-style-type: none"> • 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 	<p>Excellence, Dr. Reddy's Laboratories</p> <p>RAM KUMAR, Director MSTG, Cipla</p> <p>NARENDIRA KUMAR, Senior General Manger (Quality) Site Quality Head, Viatrix</p>
<i>QUALITY & RISK</i>		
14:50	<p>Presentation – Quality culture excellence</p> <ul style="list-style-type: none"> • To transform from "Compliance led" to "excellence led". • Guidance and tools for cultural assessment • Few QMS elements as Quality Culture enablers 	<p>Speaker</p> <p>NARENDIRA KUMAR, Senior General Manger (Quality) Site Quality Head, Viatrix</p>
15:20	<p>Coffee Break</p>	
<i>RWD & RWE</i>		
15:40	<p>Presentation – RWD & RWE - Creating value from next-generation real-world evidence</p> <ul style="list-style-type: none"> • 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? • 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 	<p>Speaker</p> <p>KAVITA LAMROR, Expert, Real World Investigator & RWD Product Owner, Sanofi</p>

	<ul style="list-style-type: none"> Market access for innovative medicines in emerging markets 	
<i>ROADMAP TO 2024</i>		
16:10	<p>Panel Discussion – Future in Manufacturing – Roadmap to 2024 – Moving forward</p> <ul style="list-style-type: none"> 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- How trackwise, Edms,LMS,LIMs to be maintained for successful audit outcome? Overcoming regulatory constraints 	<p>Moderator:</p> <p>SANDHYA PITTALA, Founder and COO, Crenza Pharmaceuticals</p> <p>Panelists:</p> <p>RAJENDAR BURKI, Associate Vice President, (R&D), Biological E. Limited</p> <p>K. SURESH BABU, Vice President- Quality Assurance, NATCO Pharma</p> <p>RAHUL MITTAL, Head Strategy - Emerging Markets, Dr. Reddy's Laboratories</p> <p>VIVEK JHA, Head - Strategy and Operations, Global Drug Development -India, Novartis</p>
17:10	Break	
PACKAGING, LABELLING, SERIALISATION, TRACK & TRACE		
18:30	Panel Discussion –	Moderator:

	<p>PPLST – Pharma Packaging Labelling Serialisation Track & Trace – Where are we heading? Which way is the right direction to improve?</p> <ul style="list-style-type: none"> • 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 	<p>Panelists:</p> <p>CHANDI PRASAD RAVIPATI, Head - Packaging Development, Aurobindo Pharma</p> <p>SEKHAR BABU PULI, Head - Packaging Development, MSN Laboratories</p>
19:30	Networking Cocktail Dinner	