

**Day-1 Sep-18, 2014**  
**Inaugural Session - Technical Seminars**

9:00 – 9:30 hrs	<b>Registration</b>
9:30 – 10:45 hrs	<b>Inaugural Session</b>
<p><b>Addresses by</b></p> <ol style="list-style-type: none"> <li>1. Shri. Sudhanshu Pandey, IAS, Joint Secretary, Dept. of Commerce, Govt. of India</li> <li>2. Shri. QF Cesar Martin Amaro Squarez, Director General, DIGEMID, Ministry of Health, Peru</li> <li>3. Dr. Hemant Koshia, Commissioner, FDA, Gujarat</li> <li>4. Dr. B L Meena, IPS, Director General, Drugs Control, Govt. of AP</li> <li>5. Dr. YK Gupta, Professor and Head, Dept. of Pharmacology, AIIMS, New Delhi</li> <li>6. Dr Muthyala Ramaiah, President / CEO, Indian Organization for Rare Diseases</li> </ol>	
10:45 – 11:00 hrs	<b>Tea Break</b>

<b>TRACK-1</b>	
<b>Best - Practice Pharmaceutical Quality System - The Way Forward for Quality Culture and Compliance</b>	
Chairman : Mr. S M Mudda Co-Chairmen : Dr. S Eswara Reddy, Dr. S S Lamba Coordinator : Dr. A R M Rao	
11:00 – 11:45 hrs	<b>Creating and Implementing a Sustainable Quality Culture</b> Mr. SM Mudda, Executive Director, Micro Labs, Bangalore
11:45 – 12:45 hrs	<b>Data Integrity – Regulatory Perspective</b> Dr. Ajaz Hussain, Ex-US FDA and Consultant
12:45 – 13:45 hrs	<b>Lunch Break</b>
13:45 – 14:30 hrs	<b>Regulatory Health Authority expectations for electronic record controls in a chromatographic laboratory</b> Ms. Heather Longden, Sr. Manager – Waters, USA
14:30 – 15:30 hrs	<b>Quality Risk Management – A Practical Approach</b> Mr. Eduardo Heidelberg, Consultant, USA
15:30 – 16:15 hrs	<b>Product Quality Life Cycle Implementation (PQLI) – Foundation of Product Quality</b> Mr. Bruce Davis, Consultant, UK
16:15 – 16:30 hrs	<b>Tea Break</b>
16:30 – 17:15 hrs	<b>Laboratory Investigations - leading to root cause.</b> Dr. Suraj Baloda, GMP Consultant
17:15 – 18:00 hrs	<b>Panel Discussion</b>

<b>TRACK-2</b>	
<b>Drugs for Rare Diseases - Govt. Initiatives &amp; Global Opportunities</b>	
Chairman : Dr. Muthyala Ramaiah Co-Chairman : Dr. Y K Gupta Coordinators : Dr. Dinesh Bharadwaj, Dr. Krishnaji Rao	
11:30 – 12:00 hrs	<b>Welcome Address</b> Dr Muthyala Ramaiah, President / CEO, Indian Organization for Rare Diseases
12:00 - 12:20 hrs	<b>Key Note Address</b> Dr. YK Gupta, Professor and Head, Dept. of Pharmacology, AIIMS, New Delhi
12:20 – 12:40 hrs	<b>International Rare Disease Research Consortium</b> Dr. Durhane Wong – Reiger CORD, Canada
12:40 – 13:00 hrs	<b>Populations – Health – Genomics – Public Health</b> Mr. Hugh Dawins, Health Development, Australia
13:00 – 14:00 hrs	<b>Lunch Break</b>
14:00 – 14:20 hrs	<b>Orphan Drug – Perspective from USFDA</b> Mr. Michael Frost, US Office of Orphan Product Development
14:20 – 15:10 hrs	<b>Orphan Drug – Indian Perspective</b> Dr. S Eswara Reddy, CDSCO, India
15:10 - 15:30 hrs	<b>All about patents of Orphan Drugs</b> Dr. GG Nair, Advisor, Pharmexcil
15:30 – 16:00 hrs	<b>Tea Break</b>
16:00 – 16:20 hrs	<b>Rare Diseases in India – Patient Support Group</b> Mr. Navaneetham Duraiswamy, Foundation for Research on Rare Drugs
16:20 – 16:40 hrs	<b>Patients – The Unheard Voices</b> Dr. Ratna Devi, Chief Executive Officer, Dakshayani and Amaravati Health and Education
16:40 – 17:00 hrs	<b>Ataxia – Patient Perspectives</b> Mr. Chandu Geroge, Seek a Miracle Ataxia Group, India
17:00 - 17:20 hrs	<b>Vision Medical Foundation for Rural Health and Research Field Experience</b> Dr. Jyothi Patel, MD, Bardoli, Gujarat
17:20 - 17:40 hrs	<b>Patients Perspective &amp; Plasma Derivatives</b> Ms. Ruby Chawla, Founder & President, Indian Patients Society for Primary Immunodeficiency
17:40 – 18:00 hrs	<b>Panel Discussion</b>

<b>TRACK-1</b> <b>Best - Practice Pharmaceutical Quality System - The Way Forward for Quality Culture and Compliance</b> Chairman : Mr. S M Mudda Co-Chairmen : Dr. S Eswara Reddy, Dr. S S Lamba Coordinator : Dr. A R M Rao		<b>TRACK-2</b> <b>Drugs for Rare Diseases - Govt. Initiatives &amp; Global Opportunities</b> Chairman : Dr. Muthyala Ramaiah Co-Chairman : Dr. Y K Gupta Coordinators : Dr. Dinesh Bharadwaj, Dr. Krishnaji Rao	
9:30-10:15 hrs	<b>Current Challenges in QA for Global Pharmaceutical Companies</b> Dr. Ludka Fyles, EUQP, UK	9:30-10:00 hrs	<b>Indian Initiative – Drug Development</b> Ms. Bhawna Sharma, Head of DNDi India
10:15 – 11:00 hrs	<b>Effective CAPA System for Continual improvement</b> Mr. Peter Galla, GMP Consultant, Quantic Group, USA	10:00-10:30 hrs	<b>Industrial Scope and efforts</b> Dr. A K S Bhujanga Rao, Natco Pharma, Hyderabad
11:00 – 11:15 hrs	<b>Tea Break</b>	10:30 – 11:00 hrs	<b>Role of Biotechnology in Orphan Drugs</b> Mr. Mahesh Gowrishankara, Director - Business Strategy Biocon, Bangalore
11:15 – 12:00 hrs	<b>Quality Metrics</b> Mr. Ranjit Barshikar, GMP Consultant	11:00 – 11:15 hrs	<b>Tea Break</b>
12:00 – 12:45 hrs	<b>Documentation practices – the nerve centre of GMP</b> Dr. Suraj Baloda, GMP Consultant	11:15 – 12:00 hrs	<b>Global Marketing Opportunities for Orphan Drugs</b> Mr. Lanka Srinivas, Sr. Advisor, Pharmexcil
12:45 – 13:30 hrs	<b>Panel discussion</b>	12:00 – 12: 30 hrs	<b>Genetics – Commercial Opportunities</b> Ms. Anupama Acharya, Mapmygenome
13:30- 14:30 hrs	Lunch Break	12:30 – 13: 30 hrs	<b>Panel Discussion</b>
14:30-15:15 hrs	Annual General Body Meeting		
15:15-15:30 hrs	Tea Break		
<b>10th Annual Celebrations</b>			
15:30-17:30 hrs	Address by Guests / Chief Guest : <b>Shri Rajeev Kher, IAS</b> , Secretary, Department of Commerce Distribution of Export / Patent Awards		
17:30-18:00 hrs	<b>Felicitation of Past Chairmen of Pharmexcil :</b> <b>Shri D B Mody</b> , J B Chemicals & Pharmaceuticals Ltd <b>Shri Venkat Jasti</b> , Suven Life Sciences Ltd <b>Shri Smitesh Shah</b> , Calyx Chemicals & Pharmaceuticals Ltd <b>Shri N R Munjal</b> , Ind-Swift Laboratories Ltd		
18:00-19:30 hrs	<b>CEOs Conclave : Theme - "My Success Story"</b> <b>Felicitation / Address by</b> a). <b>Mr. Satish Reddy</b> – Managing Director, Dr. Reddy's Laboratories Ltd c). <b>Mr. Ramaprasad Reddy</b> , Chairman, Aurobindo Pharma Ltd b). <b>Mr. Dilip Shanghvi</b> , Managing Director, Sun Pharma Ltd d). <b>Mr. Pankaj Patel</b> , Chairman & Managing Director, Cadila Health Care Ltd		
19:30 onwards	Cultural Program Dinner		