



**18<sup>th</sup> and 19<sup>th</sup> September -2014 at Hotel Park Hyatt, Hyderabad**

**TECHNICAL SEMINARS**

**Best - Practice Pharmaceutical Quality System - The Way Forward for Quality Culture and Compliance**

**Drugs for Rare Diseases - Govt. Initiatives & Global Opportunities**

**Export and Patent Awards**

**Felicitation of Past Chairmen of Pharmexcil**

**Shri D B Mody**, J B Chemicals & Pharmaceuticals Ltd  
**Shri Venkat Jasti**, Seven Life Sciences Ltd  
**Shri Smitesh Shah**, Calyx Chemicals & Pharmaceuticals Ltd  
**Shri N R Munjal**, Ind-Swift Laboratories Ltd

**Felicitation of CEOs of Top Indian Pharma Exporting Companies**

**Mr. Satish Reddy**, Dr. Reddy's Laboratories Ltd, **Mr. Ramaprasad Reddy**, Aurobindo Pharma Ltd,  
**Mr. Dilip Shanghvi**, Sun Pharma Ltd, **Mr. Pankaj Patel**, Cadila Healthcare Ltd.

**Chief Guest**

**Shri Rajeev Kher, IAS**, Secretary, Department of Commerce, Ministry of Commerce & Industry, Govt. of India

**Guests of Honour**

**Shri Sudhanshu Pandey, IAS**, Joint Secretary (Pharma), Department of Commerce, Ministry of Commerce & Industry, Govt. of India  
**Dr G N Singh**, Drugs Control General of India, CDSCO  
**Dr T S Rao**, Senior Adviser, Department of Bio-Technology  
**Shri Amit Khare**, Member Secretary, NPPA

## About Seminar

### SEMINAR HIGHLIGHTS

The Seminar is designed to provide an insight in developing a Roadmap for creating, implementing and sustaining a culture of Quality. The Seminar will be lead by eminent global quality management thought leaders.

#### 1. Best - Practice Pharmaceutical Quality System - The Way forward for Quality Culture and Compliance

- a. Creating and implementing a sustainable quality culture
- b. Data integrity - Regulatory perspective
- c. FDA expectations on Part-11 compliance in analytical lab
- d. Laboratory investigations
- e. Product quality life cycle implementation
- f. Current challenges in QA for Global Pharma companies
- g. Quality Metrics
- h. Effective CAPA system for continual improvement

#### 2. Drugs for Rare Diseases - Govt. Initiatives & Global Opportunities

- a. Rare diseases past, present and future
- b. Medical education on orphan drugs
- c. Orphan drugs - Perspective from FDA
- d. Populations - health genomes - public health
- e. Foundation for research on rare disorders
- f. Global opportunities

### WHO WILL BENEFIT

#### 1. Best - Practice Pharmaceutical Quality System - The Way forward for Quality Culture and Compliance

Quality Managers, Operational Heads, Technical Directors, Factory Managers, Heads of Regulatory Affairs

#### 2. Drugs for Rare Diseases - Govt. Initiatives & Global Opportunities

R&D Heads, Clinical Research/Pharmacology professionals, Regulators, Government Policy Makers, Rare Disease Associations.

**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>
<b>Addresses by</b>	
1. Shri. Sudhanshu Pandey, IAS, Joint Secretary, Dept. of Commerce, Govt. of India	
2. Shri. QF Cesar Martin Amaro Squarez, Director General, DIGEMID, Ministry of Health, Peru	
3. Dr. Hemant Koshia, Commissioner, FDA, Gujarat	
4. Dr. B L Meena, IPS, Director General, Drugs Control, Govt. of AP	
5. Dr. YK Gupta, Professor and Head, Dept. of Pharmacology, AllMS, New Delhi	
6. Dr Muthyala Ramaiah, President / CEO, Indian Organization for Rare Diseases	
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 – 16:15hrs	<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		

**REGISTRATION:**

Fee for technical seminars: Participants of member company Rs. 3000 + service tax per delegate

Participants of non member company Rs. 5000 + service tax per delegate

For registration please visit to our website [www.pharmexcil.com](http://www.pharmexcil.com)

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