Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

Regional GMP Strengthening Workshop for Indian Pharmaceutical Manufacturers and State Regulators

Focused on GMP in production of Active Pharmaceutical Ingredients and Oral Solid Dosage Forms

Organized in co-operation with WHO with MHRA expert support

February 19, 2015

Venue: Vivanta by Taj- Connemara, Chennai

TENTATIVE PROGRAMME

8:45-9:15 Hrs: Registration

9:15 –10:15 HRS	**INAUGURAL SESSION**
	Welcome Remarks ➢ FICCI Opening Address ➢ *Dr Nata Menabde, WHO Representative to India Special Address ➢ Mr. S. V. Veeramani, President, Indian Drug Manufacturers Association & Chairman, Fourrts (India) Laboratories Pvt Limited Special Address ➢ Dr. V K Subburaj, Secretary, Department of Pharmaceuticals Inaugural Address ➢ *Shri Ananth Kumar, Hon'ble Minister of Chemicals & Fertilizers
10:15 – 10:30 HRS	**Coffee/Tea Break**
10:30 -10:50 Hrs	**Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme** ➢ Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office ➢ Dr. Milan Smid, WHO Prequalification Team

10:50 – 11:30 Hrs	**Recent GMP developments and trends (PIC/S, WHO, EU, Scheme M)** ➢ Mr. Ian Thrussell, WHO ➢ Mr. David Churchward, MHRA ➢ * DCGI inspector
11:30 – 11:45 Hrs	**Coffee/Tea Break**
11:45 – 13:15 Hrs	**Experience from WHO, PIC/S and DCGI inspections in India - most common observations (experience, conclusions, remedial actions)** ➢ Dr Josee Hansen, Pharm.D., WHO/MEB ➢ Mr. Ian Thrussel, WHO ➢ *DCGI Inspector
13:15 – 13:30 Hrs	**Group Discussion**
13.30 – 14:30 Hrs	**Lunch**
14.30 – 15:30 Hrs	**Data integrity and verification** ➢ Mr. David Churchward, MHRA
15.30 – 15:45 Hrs	**Data integrity and verification – hands-on exercise led by** ➢ Mr. David Churchward, MHRA
15:45 – 16:15 Hrs	**Good Documentation Practice** ➢ Dr Josee Hansen, Pharm.D., WHO/MEB
16:15 – 16:30 Hrs	**Coffee/Tea Break**
16:30 -17:00 Hrs	**Assessment and management of cross-contamination risk** ➢ Mr. Ian Thrussel, WHO
17:00 -17:45 Hrs	**Moderated discussion** Questions-answers and specific discussion topics: • GMP culture and how to implement it • Communication of inspection outcomes and reporting • Public perception of GMP non-compliance and inspection findings
17:45 Hrs	**Close of workshop**

*To Be Confirmed