



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 17, 2015

Venue: Vivanta by Taj- President, Mumbai

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) <ul style="list-style-type: none"> ➤ 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) <ul style="list-style-type: none"> ➤ 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 <ul style="list-style-type: none"> ➤ Mr. David Churchward, MHRA
15.30 – 15:45 Hrs	Data integrity and verification – hands-on exercise led by <ul style="list-style-type: none"> ➤ Mr. David Churchward, MHRA
15:45 – 16:15 Hrs	Good Documentation Practice <ul style="list-style-type: none"> ➤ 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 <ul style="list-style-type: none"> ➤ Mr. Ian Thrussel, WHO
17:00 -17:45 Hrs	Moderated discussion Questions-answers and specific discussion topics: <ul style="list-style-type: none"> • 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