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 and MHRA expert support

We are delighted to inform you that FICCI in partnership with Department of Pharmaceuticals (DoP), Govt. of India and WHO Country Office for India is organizing a series of next three regional workshops on "GMP Strengthening for Indian Pharmaceutical Manufacturers focused on GMP in production of Active Pharmaceutical Ingredients and Oral Solid Dosage Forms" in Ahmedabad, Bangalore and Goa.

The workshop aims on capacity building of SME's in strengthening quality Management Systems and best practices for the process improvements, global regulatory requirements and compliance, including WHO GMP requirements. Several international experts of repute from WHO, MHRA will be participating in the program to share best practices, experiences & perspectives from across the globe.

The workshops will be held as per the following schedule:

<u>Date</u>	City	Venue
20th April 2015	<u>Ahmedabad</u>	The Fern, An Ecotel Hotel, Nr. Sola
		Overbridge, S.G. Highway,
		Ahmedabad
22nd April 2015	Bangalore	Hotel Royal Orchid, #1, Golf Avenue,
		Adjoining KGA Golf Course, HAL Airport
		Road, Kodihalli,
		Bangalore
24th April 2015	<u>Goa</u>	Royal Orchid Beach Resort, Uttorda Beach,
		Salcette,
		Goa







Department of Pharmaceuticals Ministry of Chemicals and Fertilizers Government of India

<u>Regional GMP Strengthening Workshop for Indian Pharmaceutical</u> <u>Manufacturers and State Regulators</u>

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

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April 20, 2015

Venue: The Fern, An Ecotel Hotel, Nr. Sola Overbridge, S.G. Highway, Ahmedabad

TENTATIVE PROGRAMME

8:45-9:15 Hrs: Registration

9:15 -10:15 HRS	INAUGURAL SESSION	
	Welcome Remarks	
	> FICCI	
	Opening Address Pr. Milan Smid, Group Lead, Technical Assistance and Laboratory Services, Prequalification Team, WHO	
	Special Address	
	Mr. S. V. Veeramani, President, Indian Drug Manufacturers Association & Chairman, Fourrts (India) Laboratories Pvt Limited	
	Special Address	
	Mr. Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals	
	Inaugural Address	
	 *Shri Hansraj Gangaram Ahir, Hon'ble Union Minister of State for Chemicals & Fertilizers, Government of India 	
	Vote of Thanks	
	 Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office 	
10:15 - 10:30 HRS	Coffee/Tea Break	

10:30 -10:50 Hrs 10:50 - 11:30 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, Group Lead, Technical Assistance and Laboratory Services, Prequalification Team, WHO Recent GMP developments and trends (PIC/S, WHO, EU, Scheme M) ➤ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO ➤ Mr. David Churchward, Expert Inspector, MHRA ➤ *Drug Inspector, CDSCO	
11:30 - 11:45 Hrs	Coffee/Tea Break	
11:45 - 13:00 Hrs	Experience from WHO, PIC/S and DCGI inspections in India - most common observations (experience, conclusions, remedial actions) Dr Josee Hansen, Senior Advisor, Department of Essential Medicines and Health Products, Former Chief Inspector at the Dutch Health Care Inspectorate Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO *Drugs Inspector, CDSCO	
13:00 - 13:15 Hrs	Group Discussion	
13.15 - 14:15 Hrs	Lunch	
14:15 - 14:45 Hrs	Good Documentation Practice ➤ Dr Josee Hansen, Senior Advisor, Department of Essential Medicines and Health Products, Former Chief Inspector at the Dutch Health Care Inspectorate	
14:45 - 16:00 Hrs	Data integrity and verification, including hands-on exercise ➤ Mr. David Churchward, Expert Inspector, MHRA	
16:00 - 16:15 Hrs	Coffee/Tea Break	
16:15 -17:00 Hrs	Assessment and management of cross-contamination risk ➤ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, 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 Close of workshop 	

^{*} To Be Confirmed







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April 24, 2015

Venue: Royal Orchid Beach Resort, Uttorda Beach, Salcette, Goa

TENTATIVE PROGRAMME

8:45-9:15 Hrs: Registration

9:15 -10:15 HRS	INAUGURAL SESSION	
	Welcome Remarks	
	> FICCI	
	Opening Address Dr. Milan Smid, Group Lead, Technical Assistance and	
	Laboratory Services, Prequalification Team, WHO	
	Special Address	
	*Mr. S. V. Veeramani, President, Indian Drug Manufacturers Association & Chairman, Fourrts (India) Laboratories Pvt Limited	
	Special Address	
	*Dr. R S Kamat, Director General, Goa Chamber of Commerce and Industry	
	Inaugural Address	
	Shri Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals	
	Vote of Thanks	
	Dr Madhur Gupta, Technical Officer- Pharmaceuticals,	
	WHO India Country Office	
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April 22, 2015

Venue: Hotel Royal Orchid, #1, Golf Avenue, Adjoining KGA Golf Course, HAL Airport Road, Kodihalli, Bangalore

TENTATIVE PROGRAMME

8:45-9:15 Hrs: Registration

9:15 -10:15 HRS	INAUGURAL SESSION	
	Welcome Remarks	
	> FICCI	
	Opening Address	
	Dr. Milan Smid, Group Lead, Technical Assistance and	
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	Special Address	
	*Mr. S. V. Veeramani, President, Indian Drug Manufacturers Association & Chairman, Fourrts (India) Laboratories Pvt Limited	
	Special Address	
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	*Shri Hansraj Gangaram Ahir, Hon'ble Union Minister of State for Chemicals & Fertilizers, Government of India	
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