**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:

| **Date** | **City** | **Venue** |
|---|---|---|
| **20th April 2015** | **Ahmedabad** | **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** | **Goa** | **Royal Orchid Beach Resort, Uttorda Beach, Salcette, Goa** |

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 and MHRA expert support***

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

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|---|---|
| **10:30 -10:50 Hrs** | **Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme**<br>➢ Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office<br>➢ Dr. Milan Smid, Group Lead, Technical Assistance and Laboratory Services, Prequalification Team, WHO |
| **10:50 – 11:30 Hrs** | **Recent GMP developments and trends (PIC/S, WHO, EU, Scheme M)**<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO<br>➢ Mr. David Churchward, Expert Inspector, MHRA<br>➢ *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)**<br>➢ Dr Josee Hansen, Senior Advisor, Department of Essential Medicines and Health Products, Former Chief Inspector at the Dutch Health Care Inspectorate<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO<br>➢ *Drugs Inspector, CDSCO |
| **13:00 – 13:15 Hrs** | **Group Discussion** |
| **13.15 – 14:15 Hrs** | **Lunch** |
| **14:15 – 14:45 Hrs** | **Good Documentation Practice**<br>➢ 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**<br>➢ 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**<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO |
| **17:00 -17:45 Hrs** | **Moderated discussion**<br>Questions-answers and specific discussion topics:<br>• GMP culture and how to implement it<br>• Communication of inspection outcomes and reporting<br>• Public perception of GMP non-compliance and inspection findings |
| **17:45 Hrs** | **Close of workshop** |

* To Be Confirmed

**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 and MHRA expert support***

***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<br>➢ FICCI<br><br>Opening Address<br>➢ Dr. Milan Smid, Group Lead, Technical Assistance and Laboratory Services, Prequalification Team, WHO<br><br>Special Address<br>➢ *Mr. S. V. Veeramani, President, Indian Drug Manufacturers Association & Chairman, Fourrts (India) Laboratories Pvt Limited<br><br>Special Address<br>➢ *Dr. R S Kamat, Director General, Goa Chamber of Commerce and Industry<br><br>Inaugural Address<br>➢ Shri Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals<br><br>Vote of Thanks<br>➢ Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office |
| **10:15 – 10:30 HRS** | **Coffee/Tea Break** |

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|---|---|
| **10:30 -10:50 Hrs** | **Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme**<br>➢ Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office<br>➢ Dr. Milan Smid, Group Lead, Technical Assistance and Laboratory Services, Prequalification Team, WHO |
| **10:50 – 11:30 Hrs** | **Recent GMP developments and trends (PIC/S, WHO, EU, Scheme M)**<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO<br>➢ Mr. David Churchward, Expert Inspector, MHRA<br>➢ *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)**<br>➢ Dr Josee Hansen, Senior Advisor, Department of Essential Medicines and Health Products, Former Chief Inspector at the Dutch Health Care Inspectorate<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO<br>➢ *Drugs Inspector, CDSCO |
| **13:00 – 13:15 Hrs** | **Group Discussion** |
| **13.15 – 14:15 Hrs** | **Lunch** |
| **14:15 – 14:45 Hrs** | **Good Documentation Practice**<br>➢ 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**<br>➢ 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**<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO |
| **17:00 -17:45 Hrs** | **Moderated discussion**<br>Questions-answers and specific discussion topics:<br>• GMP culture and how to implement it<br>• Communication of inspection outcomes and reporting<br>• Public perception of GMP non-compliance and inspection findings |
| **17:45 Hrs** | **Close of workshop** |

* To Be Confirmed

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 and MHRA expert support***

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

| | |
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| **10:30 -10:50 Hrs** | **Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme**<br>➢ Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office<br>➢ Dr. Milan Smid, Group Lead, Technical Assistance and Laboratory Services, Prequalification Team, WHO |
| **10:50 – 11:30 Hrs** | **Recent GMP developments and trends (PIC/S, WHO, EU, Scheme M)**<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO<br>➢ Mr. David Churchward, Expert Inspector, MHRA<br>➢ *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)**<br>➢ Dr Josee Hansen, Senior Advisor, Department of Essential Medicines and Health Products, Former Chief Inspector at the Dutch Health Care Inspectorate<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO<br>➢ *Drugs Inspector, CDSCO |
| **13:00 – 13:15 Hrs** | **Group Discussion** |
| **13.15 – 14:15 Hrs** | **Lunch** |
| **14:15 – 14:45 Hrs** | **Good Documentation Practice**<br>➢ 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**<br>➢ 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**<br>➢ Mr. Ian Thrussel, Senior Inspector, Prequalification Team, WHO |
| **17:00 -17:45 Hrs** | **Moderated discussion**<br>Questions-answers and specific discussion topics:<br>• GMP culture and how to implement it<br>• Communication of inspection outcomes and reporting<br>• Public perception of GMP non-compliance and inspection findings |
| **17:45 Hrs** | **Close of workshop** |

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