



**World Health
Organization**

**WORKSHOP ON
GMP REGULATORY INSPECTION USING QUALITY
RISK MANAGEMENT APPROACH (BASIC)
AT PUNE, MAHARASHTRA, INDIA**

for

**Newly joined Drugs Inspectors of CDSCO
State Drugs Inspectors and
Drug Testing Laboratory**

From 18th TO 22nd NOVEMBER 2013

This workshop on **“GMP REGULATORY INSPECTION USING QUALITY RISK MANAGEMENT APPROACH (BASIC)”** was held in collaboration with World Health Organization to upgrade the knowledge of newly joined Drugs Inspectors of Central Drugs Standard Control Organization along with the officers from State Drugs Control Departments and Laboratories personnel in with respect of regulatory Inspection of applying quality risk management approach.

The first phase of this workshop on **“GMP Regulatory Inspection using Quality Risk Management Approach (Basic)”** was held in Hyderabad.

Expected outcomes of the workshop is that all regulatory inspectors inspecting vaccine manufacturers will improve their skills in conducting competent and efficient GMP inspections using risk management approach and will update their knowledge on GMP requirements.

AGENDA

Day1	Day 2	Day 3	Day 4	Day 5
Opening, welcome and introduction	Warm up and program of the day	Warm up and program of the day	Mock inspection	Post Workshop Assessment Test
Module 1: Ensuring vaccine quality	Module 4; Validation Principles	Module 8: GMP Requirements for Aseptic Processing		Finalization of the report and presentation
Photo session Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break		Tea/Coffee Break
Regulatory inspection in India	Module 5: Process Validation	Module 9: Simulation study, Media Fill		Finalization of the report and presentation continue
Lunch Break	Lunch Break	Lunch Break		Lunch Break
Warm up	Warm up	Warm up		Warm up
Module 2: GMP, main concept	Module 6: Clean room and HVAC system	Module 10: Risk Based Inspection Process		Closing and distribution of certificates
Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break		
Module 3: QRMS (Concept & Basic Principles)	Module 7: Water System	Module 11: Planning for mock Inspection		
Evaluation of the day	Evaluation of the day	Evaluation of the day		
Facilitators meeting	Facilitators meeting	Facilitators meeting		

List of Participants in the training on "GMP Regulatory inspection Using Quality Risk Management Approach (Basic)"

Sr. No.	Name of Participation	Office Address	Designation
Facilitators from WHO			
1.	Dr. Alireza Khadem	WHO, Geneva	
2.	Dr. Hamid Hozuri	WHO/TA, Iran	
3.	Ms. Helena Baiao		
4.	Ms. Shanti Sibuea	WHO/TA, Indonesia	
5.	Ms. Maria Bernadette Yap	Secretary WHO	
6.	Dr. V.G. Somani	CDSCO, WZ , Mumbai	JDC (I)
7.	Mrs. Rubina Bose	CDSCO, HQ, New Delhi	ADC (I)
Facilitators from CDSCO			
1.	Mr. Shanti Prashnna Nath Singh	CDSCO, EZ	Drugs Inspector
2.	Mr. Manish Singhal	CDSCO, HQ	Drugs Inspector
3.	Mr. P. A. Jagtap	CDSCO, WZ	Drugs Inspector
4.	Mr. Vinay Kumar Gupta	CDSCO, HQ	Drugs Inspector
5.	Mr. Susant Sharma	CDSCO, Chandigarh	Drugs Inspector
6.	Mr. P. Mannavalan	CDSCO, Chandigarh	Drugs Inspector
7.	Mr. S. John Gerard	CDSCO, HQ	Drugs Inspector
Sr. No.	Name of Participation	Office Address	Designation
Participants from CDSCO			
1.	Mr. Roshan Lal Meena	CDSCO, Hyderabad	Drugs Inspector
2.	Mr. Chandrashekhar	CDSCO, Hyderabad	Drugs Inspector
3.	Mr. Shyam Narayan Singh	CDSCO, Hyderabad	Drugs Inspector
4.	Mr. Chandrashekhar Anaji Pawar	CDSCO, Hyderabad	Drugs Inspector
5.	Mr. Dileep Kumar	CDSCO, HQ	Drugs Inspector
6.	Mr. Rakesh Negi	CDSCO, HQ	Drugs Inspector
7.	Mr. Devendra Nath	CDSCO, HQ	Drugs Inspector
8.	Mr. Amol Eknath Kandekar	CDSCO, HQ	Drugs Inspector
9.	Mr. Rahul Panwar	CDSCO, HQ	Drugs Inspector
10.	Mr. Ravindra Ramchandra Shripad	CDSCO, SZ	Drugs Inspector
11.	Mr. Vanam Anjaneya Mithra	CDSCO, SZ	Drugs Inspector
12.	Mr. Naveen Yadav	CDSCO, WZ	Drugs Inspector
13.	Mr. Dinesh Kumar	CDSCO, NZ	Drugs Inspector
14.	Mr. Naveen Mehta	CDSCO, EZ	Drugs Inspector

**List of Participants in the training on
“GMP Regulatory inspection Using Quality Risk Management Approach (Basic)”**

Sr. No.	Name of Participation	Office Address	Designation
15	Mr. Neeraj Katiyar	CDSCO, Ahmedabad	Drugs Inspector
16.	Mrs. D. Hemalatha	CDSCO, Bangalore	Drugs Inspector
17.	Mr. Munish Kakar	CDSCO, Chandigarh	Drugs Inspector
Participant from States			
1.	Mr. Nitin Pandurang Aher	FDA, Maharashtra	Drugs Inspector
2.	Mr. Onkareshwara B.B.	Office of Drugs Controller, Karnataka	Drugs Inspector
3.	Mr. Dobaria Vithalbhai D.	Food Drugs Control Administration, Gujarat	Drugs Inspector
4.	Mr. Thiru. A. Habeeb Mohamed	Assistant Director of the Drugs Control, Virudhunagar Zone, Chennai	Drugs Inspector
Participant from CDL			
1.	Mr Devendra Barthwal	CDL	Technical Supervisor



Official opening of the workshop was made by Dr. V. G. Somani, Joint Drugs Controller (India), CDSCO, West Zone, Mumbai



**Welcome address was made by Mrs. Rubina Bose,
Asst. Drugs Controller (India), QA.**



Photo Session with all the Facilitators & Participants

Workshop on the GMP Regulatory Inspection using Quality Risk Management Approach (Basic) started with the following:

- 1 Registration of participants and signing of confidentiality agreement by all the participants and facilitators who attended the work shop.
- 2 Official opening address by CDSCO Representatives - Dr. V. G. Somani Joint Drugs Controller (India), West Zone, Mumbai, Mrs. Rubina Bose Asst. Drugs Controller (India), HQ.
- 3 Opening address by WHO Facilitators/ Trainers Dr. Alireza. Khadem - WHO/ HQ/EMP/QSS, DR. Hamidreza Hozuri-WHO/TA, Iran and Ms. Helena Baiao.
- 4 WHO Facilitator-Ms. Shanti Sibuea-Regulator, Indonasia and Ms. Maria Bernadette Yap-Secretary WHO.
- 5 Assessment of the knowledge of the participants through Pre -assessment before training starts.
- 6 Different Modules were presented by WHO facilitators during the workshop.



Introduction and housekeeping programme of the day and week, work shop methodology and planned activities were explained by Dr. A. Khadem to the participants.



Pre-Assessment



Information on Regulatory Inspection in India presented by Ms. Rubina Bose, Asst. Drugs Controller (India) and brief about the Drugs and Cosmetics Act 1940 and rules 1945 made there under, SOPs, Guidelines and system followed by CDSCO.

Exercise of participants during the workshop with WHO facilitators



ACTIVITY DRIVEN COURSE

All the participants had warm up sessions twice every day which included physical and mental activities.





Group exercises were given during and after the presentation by facilitators to make learning interactive and interesting and easy to understand the concept of the presentation.



Evaluation was made every day by one of the participant on behalf of all the participants to get the feedback about all the presentations conducted for improving the content & methodology.

Mock Inspection was held at Vaccine manufacturing unit.
Before the closing meeting all the groups have presented the interim report on
Mock Inspection conducted





Distributing the certificate to participants



Organizer for the Workshop along with QA Division

