

The Workshop on GMP Regulatory Inspection Using Quality Risk Management Approach (Basic) for the

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

From 23rd TO 27th SEPTEMBER 2013



**GOVERNMENT OF INDIA
Ministry of Health and Family Welfare**



WORKSHOP on

"GMP Regulatory Inspection Using Quality Risk Management Approach (BASIC)"

Organized by

**Central Drugs Standard Control Organization
in collaboration with
World Health Organization**

23 - 27 September 2013

Venue: Hotel Greenpark, Begumpet & CDSCO Zonal Office, Hyderabad

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 with respect to Regulatory Inspection applying quality risk management approach.

Objective of the Workshop is to ensure that the Regulatory inspection functions of the NRA in India will be performed against the WHO recommended standards and to update the NRA IDP in order to ensure full enforcement of GMP in all Indian vaccine manufacturers.

The Workshop on the GMP Regulatory Inspection using Quality Risk Management Approach (Basic) was inaugurated on 23rd September 2013 by lighting of lamp. Official opening of the workshop was made by Shri ACS Rao, DDC (I), CDSCO, Hyderabad and Welcome address was made by Mrs. Rubina Bose, ADC (I), QA.



Lamp lighting ceremony by all the Facilitators



Official opening of the Workshop



Welcome note



Group Photograph with all the Facilitators & Participants

AGENDA

Day 1	Day 2	Day 3	Day 4	Day 5
Opening, wellcome and introduction	Warm up and program of the day	Warm up and program of the day	Mock inspection	Warm up and program of the day
Module 1: Ensuring vaccine quality	Module 4; Quality Risk Management (QRM)	Module 8:		Finalization of the report and presentation
Break	Break	Break		
Regulatory inspection in India	Module 5: Inspection, type and approach	Module 9:		
Lunch	Lunch	Lunch		Lunch
Warm up	Warm up	Warm up		Presentation and reports
Module 2: GMP, main concept	Module 6:	Module 10:		Closing and distribution of certificates
Break	Break	Break		
Module 3: QMS	Module 7:	Module 11:		
Evaluation of the day	Evaluation of the day	Evaluation of the day		
Facilitators meeting	Facilitators meeting	Facilitators meeting		

First day of In-Country Workshop on the GMP Regulatory Inspection using Quality Risk Management Approach (Basic) started with the following:

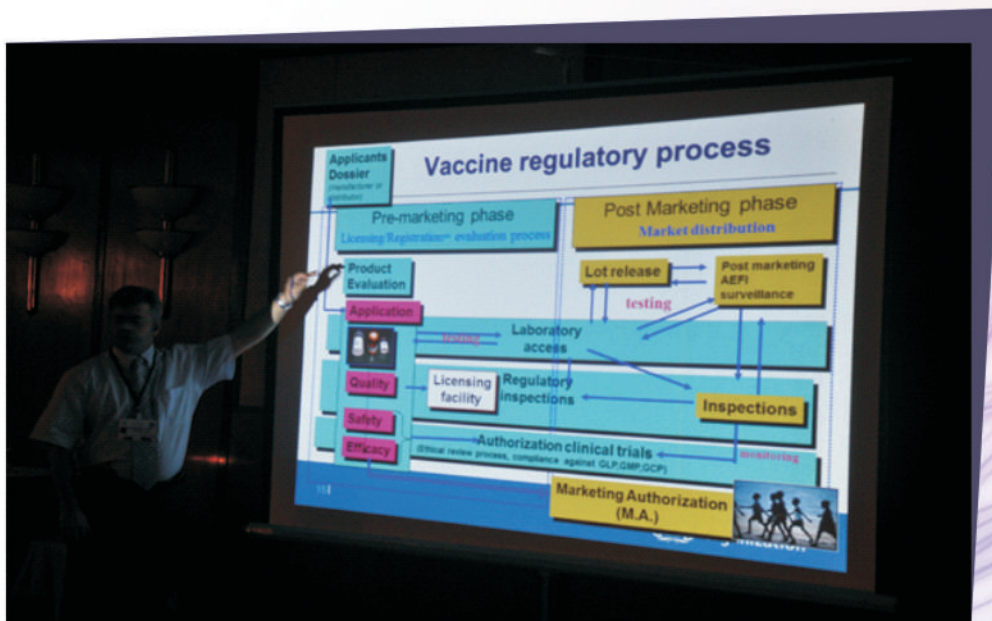
- Registration of participants and signing of confidentiality agreement by all the participants and facilitators who attended the work shop.
- Official opening address by CDSCO Representatives - Mr. A.C.S. Rao, DDC(I) Hyderabad, Mrs. Rubina Bose ADC(I), HQ, Mrs. Swati Srivastava, ADC (I), HQ.
- Opening address by WHO Facilitators/ Trainers Dr. A. Khadem - WHO/ HQ/EMP/QSS, DR. Hamidreza Hozuri-WHO/TA, Iran and Mr. Nadir Harjee- WHO/TA, Canada.
- Assessment of the knowledge of the participants through Pre -assessment before training starts.



Pre-Assessment:

Before the training starts the assessment of knowledge of participants is done.

Participants were apprised of regulatory procedures



- Introduction and housekeeping programme of the day and week, work shop methodology and planned activities were explained by Dr. A. Khadem to the participants.
- Information on WHO policy on ensuring quality of vaccines presentations delivered by Dr. A. Khadem to understand the WHO Policy on ensuring vaccine quality by implementing a regulatory system and six functions by the participants.



Activity Driven Course: All the participants had warm up sessions twice every day which included physical and mental activity.



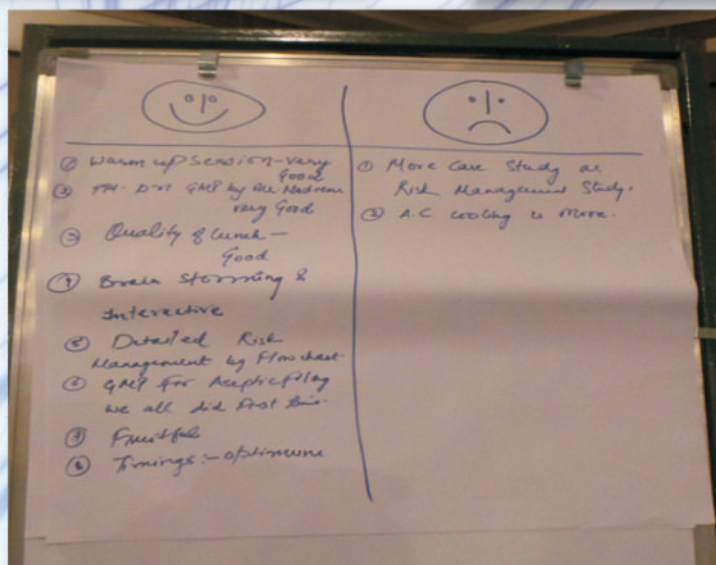
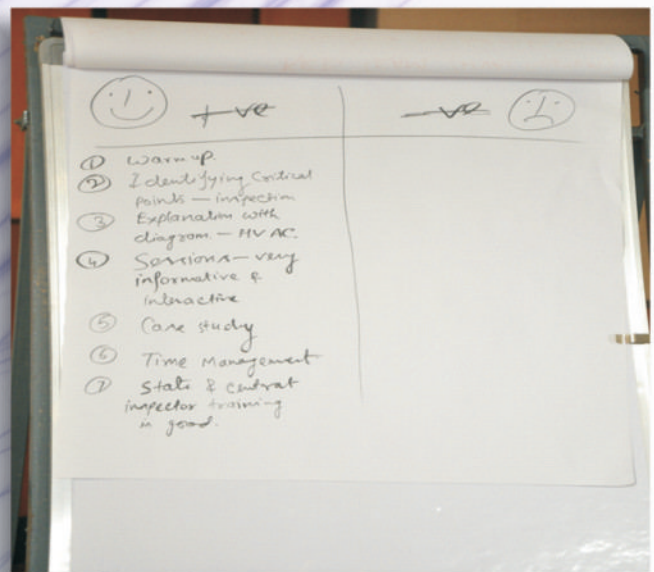
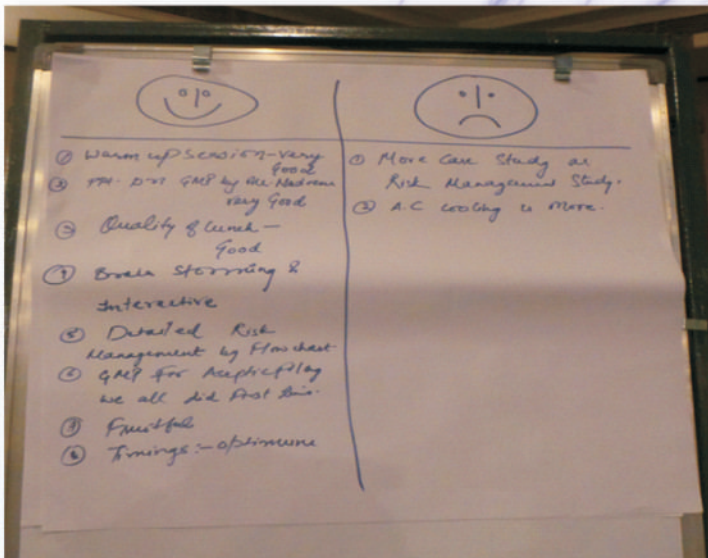
Active Participation of All Facilitators and Participants in Case Studies: Sharing Experience: Group exercises were given during and after the presentation by facilitators to make learning interactive and interesting and easy to understand the concept of the presentation.



Participants from the Central Drugs Standard Control Organisation, State Drugs control and The Government Laboratories showed keen interest in the Group Exercises and Case studies.



Evaluation for the day: It was made 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.



PRACTICAL SESSION - MOCK AUDIT



CERTIFICATE DISTRIBUTION TO PARTICIPANTS & LOCAL FACILITATORS:



Certificate Distribution to Local Facilitators by Shri P. Nagabushanam, Director, DCA, Andhra Pradesh



Certificate Distribution to Participants by Facilitators from WHO

**List of Participants in the Training on 'GMP Regulatory Inspection (Basic)'
from 23rd to 27th September, 2013 at Hyderabad**

S.No.	Name of the Participant	Office Address	Designation
Facilitators from WHO			
1	Dr. Alireza Khadem	WHO, Geneva	
2	Dr. Hamid Hozuri	WHO/TA, Iran	
3	Mr. Nadir Harjee	WHO/TA, Canada	
4	Mr. A.C.S. Rao	CDSCO, Hyderabad	DDC (I)
5	Mrs. Rubina Bose	CDSCO, HQ, New Delhi	ADC (I)
6	Ms. Swati Srivastava	CDSCO, HQ, New Delhi	ADC (I)
Facilitators from CDSCO			
1	Mr. Rahul Shakhpure	CDSCO, Hyderabad	Drugs Inspector
2	Ms. L. Suganthi	CDSCO, Hyderabad	Drugs Inspector
3	Mr. P.A.Jagtap	CDSCO, WZ	Drugs Inspector
4	Mr. Rajappan Viswanathan	CDSCO, NZ	Drugs Inspector
5	Mr.P. Dhinesh Pandian	CDSCO, HQ	Drugs Inspector
6	Ms. M.Shakuntla	CDSCO, SZ	Drugs Inspector
7	Mr.Y.K.Shelar	CDSCO, HQ	Drugs Inspector
8	Ms. Shraddha Srivastava	CDSCO, HQ	Drugs Inspector
Participants from CDSCO			
1	Mr.Ankur Bansal	CDSCO, HQ	Drugs Inspector
2	Mr.Saurabh Garg	CDSCO, HQ	Drugs Inspector
3	Ms. Nisha Kaushik	CDSCO, HQ	Drugs Inspector
4	Mr.V. Kaviyarasan	CDSCO, WZ	Drugs Inspector
5	Dr. Kashi Sankar	CDSCO, HQ	Drugs Inspector
6	Mr.Ketankumar P. Panchal	CDSCO, WZ	Drugs Inspector
7	Mr.Manish Neekhra	CDSCO, EZ	Drugs Inspector
8	Ms. Minakshi	CDSCO, NZ	Drugs Inspector
9	Ms. A. Anitha	CDSCO, SZ	Drugs Inspector
10	Mr.Mukesh Kumar	CDSCO, NZ	Drugs Inspector
11	Mr.Sourabh Mittal	CDSCO, HQ	Drugs Inspector
12	Mr.Kailash Chand Meena	CDSCO, Ahmedabad	Drugs Inspector
13	Mr.Ganesh Jangalu Nannaware	CDSCO, Ahmedabad	Drugs Inspector
14	Mr.Vinod Kumar Gupta	CDSCO, Hyderabad	Drugs Inspector
15	Mr.S. Gopinath	CDSCO, NZ	Drugs Inspector
Participants from States			
16	Mr. Kulwinder Singh	FDA, Punjab	Drugs Inspector
17	Ms Lakshmi Bommisetty	DCA, Hyderabad	Drugs Inspector
18	Mr. N. Ravi Kiran Reddy	DCA, Hyderabad	Drugs Inspector
19	Mr. Rajeev Bhargava	DCD, Delhi	Drugs Inspector
20	Mr. Kamlesh Naik	DCD, H.P.(Baddi)	Drugs Inspector