

REGULATORY INSPECTION

**QUALITY RISK MANAGEMENT APPROACH
APPLIED TO GMP INSPECTION
(BASIC)**

PUNE, INDIA

24-28 November 2014

Group photograph



Objectives

- ▶ Ensure that the regulatory inspection functions of the NRA in India will be performed against the WHO recommended standards,
- ▶ Update the NRA IDP in order to ensure full enforcement of GMP in all Indian vaccine manufacturers.

Learning objectives

At the end of the programme participants will be able :

- to discuss general elements of Quality Management and GMP for vaccine manufacturing
- to explain general principles of Quality Risk Management
- to identify key elements for inspections of GMP Systems
- to apply the risk based approach for planning and conducting GMP inspections in vaccine and biological manufacturing facilities

Program of the Week

Day 1	Day 2	Day 3	Day 4	Day 5
Opening, welcome	Warm up and program of the day	Warm up and program of the day	Mock inspection	Warm up and program of the day
Introduction and warm up	Module 4: Validation, Principals	Module 8: GMP requirements for aseptic processing		Post workshop questionnaire Finalization of the report and presentation
Break	Break	Break		
Objectives and expectations Pre-workshop questionnaire Regulatory inspection in India Module 1: Ensuring vaccine quality, WHO policy	Module 5: Validation, process validation	Module 9: Simulation study, Media Fill		
Lunch	Lunch	Lunch		Lunch
Warm up	Warm up	Warm up		Presentation and reports
Module 2: GMP Main concept	Module 6: Clean room and HVAC system	Module 10: Risk based inspection process		
Break	Break	Break		Distribution of certificates and closing
Module 3: Quality Risk Management	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		

Opening address of the Workshop



**Mrs. Emma Uramis,
WHO**



**Dr. K. Bangarurajan,
CDSCO (WZ)**



**Dr. A. Ramkishan,
CDSCO (HQ)**



**Mrs. Rubina Bose,
CDSCO (HQ)**



**Mr. B.R. Masal, Joint
Commissioner, FDA, Pune**

List of Participants

S.No.	Name	Designation	Division/Organisation
Participants from CDSCO			
1	Shri V. Sooraj	Drugs Inspector	CDSCO (HQ)
2	Shri Saurabh Jain	Drugs Inspector	CDSCO (HQ)
3	Shri Jay Jyoti Roy	Drugs Inspector	CDSCO (HQ)
4	Shri Sandeep Kumar	Drugs Inspector	CDSCO (HQ)
5	Shri Bibekananda Behera	Drugs Inspector	CDSCO (HQ)
6	Shri Pratyush Kumar	Drugs Inspector	CDSCO (HQ)
7	Shri Baljeet Singh	Drugs Inspector	CDSCO (HQ)
8	Smt. Suniti Choudhary	Drugs Inspector	CDSCO (HQ)
9	Shri Balakumar Mahalingam	Drugs Inspector	CDSCO (HQ)
10	Smt. Shyamaladevi D	Drugs Inspector	CDSCO (HQ)
11	Shri P. Selvaraj	Drugs Inspector	CDSCO (HQ)
12	Shri Sachin Yadaorao Bhagwate	Drugs Inspector	CDSCO (HQ)
13	Shri Shabeer Ashfaque Abdulla	Drugs Inspector	CDSCO (HQ)
14	Shri Rahul Singh	Drugs Inspector	CDSCO (HQ)
15	Shri Basant Kumar Yadav	Drugs Inspector	CDSCO (HQ)
16	Shri Arvind Singh Panwar	Drugs Inspector	CDSCO (HQ)
17	Ms. A. Anbuselvi	Drugs Inspector	CDSCO (HQ)
18	Mr. Saurabh Garg	Drugs Inspector	CDSCO (HQ)
Participant from CDL, Kasauli			
19	Ms. Suchita Sharma	Technical Supervisor	Central Drugs Laboratory, Kasauli
Participants from State Drugs Control Department			
20	Smt. A. M. Mitkar	Drugs Inspector	Maharashtra
21	Shri K.M. Rajne	Drugs Inspector	Maharashtra
22	Smt. Chandrika Chodvadiya	Sr. Drugs Inspector	Gujarat

Warm up Session during the workshop



Warm up Session during the workshop



Plenary sessions by Facilitators



Dr. Anna Laura Salvati
addressing the
participants



Mrs. Helena Baiiao
addressing the
participants



Mrs. Emma Uramis
addressing the
participants

Plenary sessions by Facilitators



Dr. S.E. Reddy addressing the participants



Mrs. Rubina Bose addressing the participants

Group discussions



Group discussions



Mock inspection to SIIL



Mock inspection to SIIL



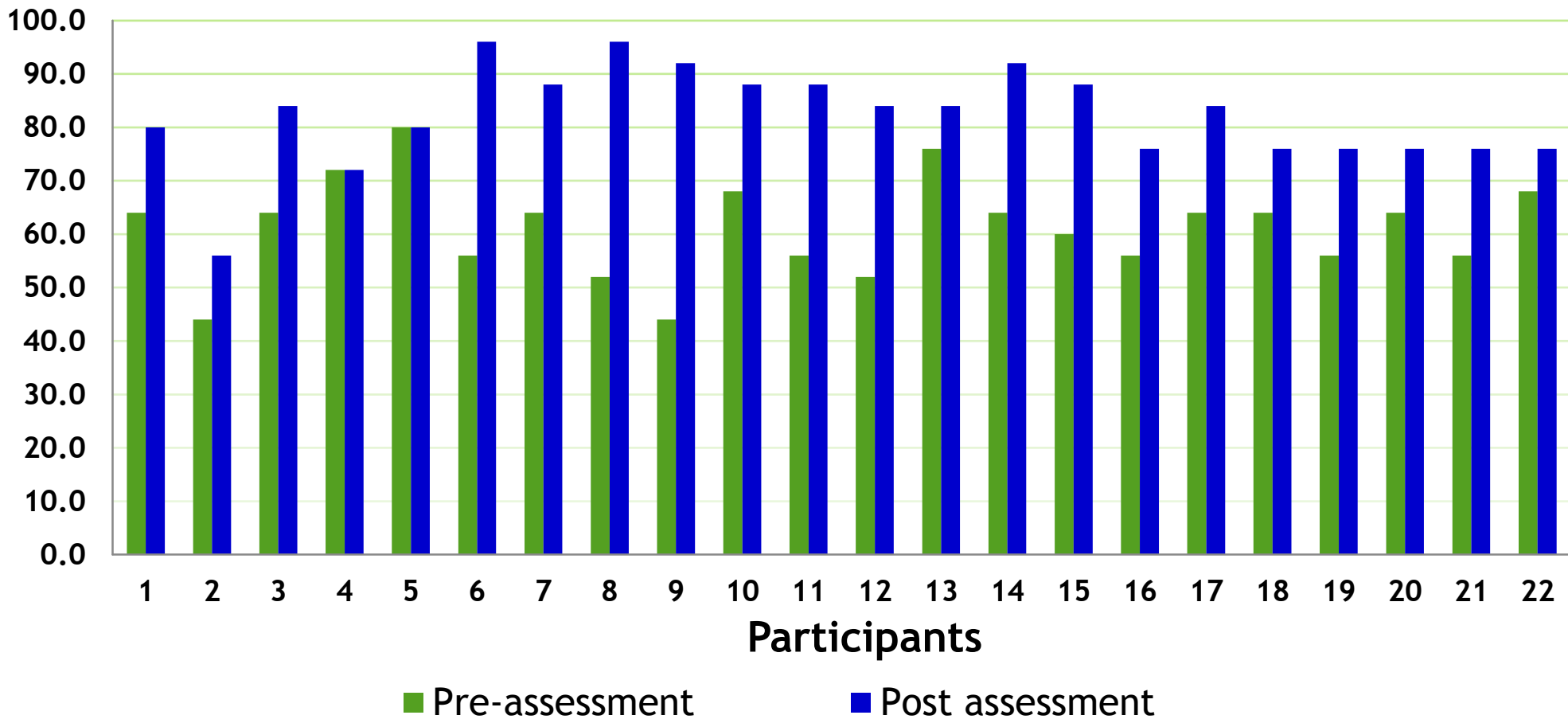
Mock inspection to SIIL



Mock inspection team at SIIL



Evaluation of participants in Pre and Post Assessment



Closing Ceremony of the workshop



Mr. D.M. Phadtare,
Joint Commissioner
(Vig.), FDA,
Maharashtra addressing
participants during
closing ceremony

