
World Health Organization
CDSCO
CDSCO
"CDSCO–WHO Workshop for GMP strengthening of State Regulatory Inspectorate"
From 27th January, 2014 to 5th February, 2014

- CDSCO planned two days "**CDSCO–WHO Workshop for GMP strengthening of State Regulatory Inspectorate"** focused on GMP of Active Pharmaceutical Ingredients and Oral Solid Dosage Forms and Good Inspection Practices in three batches at Hyderabad, Ahmedabad and Chandigarh respectively from 27th January to 5th February 2014 in collaboration with WHO HQ and WHO country office
- The workshops had been funded by WHO country office. The training was imparted by International experts from WHO HQ, USFDA and MHRA.
- The participants of the workshop were the Heads/ Controlling officers of CDSCO and State Drugs Control Organization who are responsible for imparting training to the Inspectors working under them. There were 22 states and four union territories viz. Maharashtra, Gujarat, Madhya Pradesh, Chhattisgarh, Rajasthan, Andhra Pradesh, Karnataka, Tamil Nadu, Uttar Pradesh, Uttarakhand, Himachal Pradesh, Puducherry, Delhi, Silvassa, Daman and Diu, Kerala, West Bengal, Assam, Orissa, Jharkhand Sikkim and total 96 Participants at the level of Deputy Director, Assistant Director, Senior Drugs Inspectors, Drugs inspectors including Drugs Controller of Himachal Pradesh, Punjab, Haryana and Rajasthan joined the two days workshop from all over India.
- 18 Senior Officers from CDSCO (HQ), North Zone, South Zone, West Zone, Ahmedabad Hyderabad, subzone Goa and Chandigarh also participated in the Workshop.

- **OBJECTIVES OF THE WORKSHOP**
- A large number of Drugs Inspectors have been recruited in both Central and State level. They are often deputed to participate in the inspection of various manufacturing facilities. The workshop has been envisaged to improve the inspection and training skills of the Heads/ Controlling officers of Indian drug regulators based on advanced GMP for imparting training to the newly recruited Drugs Inspectors at the central and State level as a part of capacity building to the Indian Regulatory System.
- All participants will gain a fundamental knowledge of the basis of GMP regulations focused on API and Oral Solid Dosage forms, and the necessity of implementing them in daily operations. Additionally, this workshop is intended to give participants an introduction to the GMP regulations and their application to laboratory activities, manufacturing processes and support functions, as well as demonstrate the need for thorough and comprehensive GMP training and documentation. The workshop will also provide the participants with an understanding of common terminology and the role GMPs in their day-to-day responsibilities. Focus is given to the regulatory nature of GMP compliance, managing the implementation of GMP efforts, proactively sustaining a culture of compliance in all scientific and manufacturing

efforts and recent GMP failure and debarring of many Indian API Manufacturers by International regulators

The other objectives of this workshop are as given below:

Strengthening of Indian GMP standards through convergence of standards, effective, correct interpretation and application of standards

-Fostering co-operation through better communication and exchange of information to build mutual confidence between participating regulators

-Sharing of inspection findings of the Indian manufacturers with CDSCO and relevant State Drugs Control in regular manner for information and regulatory decision if required as per Drugs and Cosmetic Act and Rules

-To improve the skills in conducting competent and efficient GMP inspections using risk management approach of all regulatory Inspectors supervising manufacturing.

-Capacity building of Inspectors through training, participating in inspection of Indian manufacturers carried out by International inspectors

- **SPEAKERS/ RESOURCE PERSON:**

- International experts from the WHO Pre Qualification Team for Medicines Programme, PICs, MHRA and USFDA were speakers for various technical sessions on current GMP trends and practices. Following are the details of Experts for the workshop:

1. Dr. Ian Richard Thrussel, Technical Officer (Pre Qualification Programme), World Health Organization-Geneva
2. Dr. Milan Smid, Technical Officer (Pre Qualification Programme), World Health Organization-Geneva
3. Mr. David Mark Churchward, Expert Inspector (GMDP) Medicine and Healthcare Products Regulatory Agency, London, United Kingdom.
4. Mr. Mark Birse, Group Manager (GMDP), Medicine and Healthcare Products Regulatory Agency, London, United Kingdom.
5. Ms. Farhana Khan, Asst. Director (Medicines), Office of International Programme, USFDA.
6. Dr. Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office

SPEAKERS/ RESOUECE PERSONS FOR THE WORKSHOP

- **AGENDA FOR THE WORKSHOP**

DAY- 1

Time	Topic/ Presenter
09:00-09:15	Workshop opening and introduction
09:15-09:35	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, WHO Prequalification Programme, WHO-HQ
09:35-10:15	Existing GMP standards, their similarities and major differences (PIC/S, WHO, EU, US-FDA, Schedule M) - Mr. Ian Thrussell, WHO Prequalification Programme, WHO HQ Recent GMP developments and trends - Mr. David Churchward, MHRA - DCGI Representative/s
10:15 - 10:35	**Coffee/Tea Break**
10.35 - 12:35	Experience from WHO, PIC/S and Indian **API** inspections, most common problems and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) - Mr. Mark Birse, MHRA - Ms. Farhana Khan, US FDA - Mr. Ian Thrussel, WHO PQP - DCGI representative/s Group or individual exercise to propose key subjects for general discussion
12:35 – 13.00	Group Discussion

Time	Topic/ Presenter
13.00- 14.00	**Lunch**
14:00- 15.40	Good inspection practice: • Risk based planning of GMP inspections (general plan) • Preparing plan of individual GMP inspection • Inspection conduct and dealing with serious non-compliance, data fraud, false or misleading information • Communication of inspection outcomes and reporting - Mr. David Churchward, MHRA - Mr. Ian Thrussel, WHO PQP
15:40- 16:00	**Coffee/Tea Break**
16:00- 17.30	Data integrity and data verification Learning from recent cases with international implications Co-operation and communication among inspectorates (moving from transparency to cooperation, to confidence building and reliance) - Ms. Farhana Khan, US FDA - Mr. Ian Thrussel, WHO PQP - Mr. David Chruchward, MHRA - DCGI Representative/s

DAY- 2

Time	Topic/ Presenter
Time	**Topic**
09:00- 10:40	Experience from WHO, PIC/S and Indian inspections of oral solid dosage forms manufacturers - most common problem and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) - Mr. Mark Birse, MHRA - Ms. Farhana Khan, US FDA - Mr. Ian Thrussel, WHO PQP - DCGI Representative/s Group or individual exercise to propose key subjects for general discussion
10:40- 11:00	**Coffee/Tea Break**
11:00- 11.45	Inspection of the quality system (is the QS really in place or is it a requisite to satisfy inspectors formally) - Ms. Farhana Khan, US FDA - DCGI Representative/s
11.45-12.30	Quality risk management and how inspectors assess its implementation - Mr. Ian Thrussel, WHO

Time	Topic/ Presenter
12.30-13.00	How to assess plans of corrective actions and the change management - Mr. Mark Birse, MHRA
13.00-14.00	**Lunch**
14:00-14.45	HVAC systems and assessing risk of cross contamination - Mr. David Churchward, MHRA
14.45-15:30	Management of out of specification results - Ms. Farhana Khan, US FDA - DCGI Representative/s
15:30-15.40	- Coffee/Tea Break
15.40 – 16.20	- Training of inspectors - Mr. Mark Birse, MHRA
16.20-17.00	**Moderated discussion**

INTRODUCTION AND DESCRIPTION OF THE TRAINING HELD

Part 1. : CDSCO–WHO Workshop for GMP strengthening of State Regulatory Inspectorate on 27th -28th January, 2014 at Hyderabad

Introduction

- The workshop was started with the opening address by by Ms. Rubina Bose, Asst. Drugs Controller (I), CDSCO, HQ by welcoming dignitaries and introduction of all International experts to the participants. Ms. Rubina Bose thanked all the International Experts for joining the workshop to share their knowledge and explained background of the workshop and meticulous planning of the training in the form of lectures by experts. On behalf of CDSCO, Zonal office Hyderabad Mr. S. Manivannan, Deputy Drugs Controller (I), Bangalore and In-charge Hyderabad has welcomed all the experts and participants and addressed the importance of this workshop.
- The Directorate has nominated 7 officers from different CDSCO Zones and Headquarter as participants, and 32 officers from different States.

The list of participants is as per the table given below

S. No	Name	Designation	Organization / Division
1	Mrs Rubina Bose	Assistant Drugs Controller (India), (Head Quarter)	CDSCO, Head Quarter, New Delhi
2	Ms. Shanthy Gunasekharan	Deputy Drugs Controller (India), South Zone	CDSCO, South Zone, Chennai
3	Mr. P.B.N. Prasad	Deputy Drugs Controller (India) South Zone	CDSCO, South Zone, Chennai
4	Mr. S. Manivannan	Deputy Drugs Controller (India), Bangalore	CDSCO, Sub Zonal office, Bangalore
5	Mr. Ranga Chandrashekar	Deputy Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
6	Mr. B. Kumar	Assistant Drugs Controller (India), South Zone	CDSCO, South Zone, Chennai
7	Mr. A. Senkhathir	Assistant Drugs Controller (India), South Zone	CDSCO, South Zone, Chennai
8	Mr. Ashrubindu Bhunia	Assistant Director of Drugs Control	The Director of Drugs Control, West Bengal
9	Mr. Manas Chakraborty	Drugs Inspector	The Director of Drugs Control, West Bengal
10	Mrs. Sukanya Ganguly	Senior Drugs Inspector	The Director of Drugs Control, West Bengal
11	Mr. Sanjib Samanta	Drugs Inspector	The Director of Drugs Control, West Bengal
12	Dr. I.L. Sharma	Addl. Drugs Controller	Drugs & Cosmetic Cell H.C., H.S. & F.W. Deptt. Govt. of Sikkim
13	Mr. C.N. Sharma	Joint Director-cum-Licensing Authority	Drugs & Cosmetic Cell H.C., H.S. & F.W. Deptt. Govt. of Sikkim

S. No	Name	Designation	Organization / Division
14	Mr. L.M. Targain	Sr. Drugs Inspector	Drugs & Cosmetic Cell H.C., H.S. & F.W. Deptt. Govt. of Sikkim
15	Mr. Harmohan Mohanty	Asst. Drugs Controller (Int.)	Directorate of Drugs Control, Odisha
16	Mr. Ashok Kumar Patra	Asst. Drugs Controller (Ind.)	Directorate of Drugs Control, Odisha
17	Mr. Sunil Kumar Nayak	Asst. Drugs Controller (Dev)	Directorate of Drugs Control, Odisha
18	Ms Niharika Dash	Drugs Inspector, Cuttack-III Range, Cuttack	Directorate of Drugs Control, Odisha
19	Mr. P. Hariprasad	Drugs Controller	Office of the drugs controller Thiruvanthapuram, Kerala
20	Mr. K. J. John	Assistant Drugs controller	Office of the drugs controller Thiruvanthapuram, Kerala
21	Mr. P.M. Jayan	Asst. Drugs Contoller (Intelligencne Branch)	Office of the drugs controller Thiruvanthapuram, Kerala
22	Mr. R. Uday Bhaskar	Asst. Director, Hyderabad (Mfg.)	Government of Andhra Pradesh Department of Drugs control Administration
23	Mr. K. Raja Bhanu	Asst. Director, Hyderabad (Mfg.)	Government of Andhra Pradesh Department of Drugs control Administration
24	Mr. E. Sambasiva Rao	Drugs Inspector, Balanagar (Mfg.)	Government of Andhra Pradesh Department of Drugs control Administration
25	Mr. M. Varaprasad	Drugs Inspector, Bollaram (Mfg.)	Government of Andhra Pradesh Department of Drugs control Administration

S. No	Name	Designation	Organization / Division
26	Mr. T. Shiva Teja	Drugs Inspector, Malkajgiri (Mfg.)	Government of Andhra Pradesh Department of Drugs control Administration
27	Mr. M.C. Deka	Joint Drugs Controller (HQ)	O/o the Directorate of Health Services, Assam
28	Mr. A.K. Sarma,	Senior Inspector of Drugs, Kamrup	O/o the Directorate of Health Services, Assam
29	Mr. N. Vadivelu	Deputy Drugs Controller, Head Quarters, Bangalore	Drugs Controller Department, Karnataka
30	Mr. Umesh	Assistant Drugs controller,	Drugs Controller Department, Karnataka
31	Mr. Umakanth R. Patil	Assistant Drugs Controller, Head Quarters, Bangalore	Drugs Controller Department, Karnataka
32	Mr. P. Ramesh	Assitant Drugs Controller, Head Quarters, Bangalore	Drugs Controller Department, Karnataka
33	Mr. G.V. Narayana Reddy	Assistant Drugs controller	Drugs Controller Department, Karnataka
34	Mr. K. Sivabalan	Deputy Director of Drugs Control	Office of the Director of Drugs Control, Tamil Nadu
35	Mr. R. Kannan	Drugs Inspector	Office of the Director of Drugs Control, Tamil Nadu
36	Mr. S.S. Mohamed Kamal	Drugs Inspector	Office of the Director of Drugs Control, Tamil Nadu
37	Mr. S. Sudalaivel Muragiah	Drugs Inspector	Office of the Director of Drugs Control, Tamil Nadu
38	Mr. K. Arunachalam	Deputy Director of Drugs Control	Office of the Director of Drugs Control, Tamil Nadu
39	Mr. S. K. Tiwari	Drugs Inspector	DCA Jharkhand

- **Day-wise proceeding of the workshop is as follows:**
- **Day One – 27-01-2014**

  The agenda topics e.g. Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme, Existing GMP standards, their similarities and major differences (PIC/S, WHO, EU, US-FDA, Schedule M), Recent GMP developments and trends and Experience from WHO, PIC/S and Indian API inspections, most common problems and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) deliberated and discussed during the pre-lunch session. The agenda topics covered in the post lunch session were Good inspection practice, learning from recent cases with international implications, Co-operation and communication among inspectorates (moving from transparency to cooperation, to confidence building and reliance)

- **Day Two – 28-01-2014**

  The session was started with the agenda topic Experience from WHO, PIC/S and Indian inspections of oral solid dosage forms manufacturers - most common problem and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) followed by Inspection of the quality system (is the QS really in place or is it a requisite to satisfy inspectors formally) Quality risk management and how inspectors assess its implementation and how to assess plans of corrective actions and the change management up to the pre-lunch session. The post lunch session started with the presentation on HVAC systems and assessing risk of cross contamination followed by Management of out of specification results and Training of inspectors and ended up with the moderate discussion.

PARTICIPANTS DISCUSSED ON VARIOUS TOPICS DURING THE WORKSHOP

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GROUP PHOTOGRAPH DURING CLOSING CEREMONY AT HYDERABAD

Part 2. : CDSCO–WHO Workshop for GMP strengthening of State Regulatory Inspectorate" on 1st – 2nd February, 2014 at Ahmedabad

Introduction

- The workshop was started with the opening address by Ms. Rubina Bose, Asst. Drugs Controller (I), CDSCO, HQ by welcoming dignitaries and introduction of all International experts to the participants. Ms. Rubina Bose thanked all the International Experts for joining the workshop to share their knowledge and explained background of the workshop and meticulous planning of the training in the form of lectures by experts. On behalf of CDSCO, Zonal office Ahmedabad Dr. V.G. Somani, Joint Drugs Controller (I), has welcomed all the experts and participants and addressed the importance and objective of this workshop and highlighted the mandate, mission and vision of CDSCO, and expectation from this workshop.

- The Directorate has nominated 35 officers from different CDSCO Zones and Headquarter as participants, and 12 officers from different States.

DR. V. G. SOMANI, JOINT DRUGS CONTROLLER (I) WITH INTERNATIONAL EXPERTS DURING OPENING CEREMONY OF WORKSHOP

The list of participants is as per the table given below

S. No	Name	Designation	Organization / Division
1	Dr. V. G. Somani,	Joint Drugs Controller (India), HQ	CDSCO, HQ
2	Mrs Rubina Bose	Assistant Drugs Controller (India), (Head Quarter)	CDSCO, Head Quarter, New Delhi
3	Mr. G. Nageswara Rao,	Deputy Drugs Controller (India), Ahmedabad	CDSCO, Zonal office Ahmedabad
4	Dr. A. Ramkishan,	Deputy Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
5	Mr. Jayant Kumar,	Assistant Drugs Controller (India), West Zone	CDSCO, West Zone, Mumbai
6	Mr. B.K. Samantaray,	Assistant Drugs Controller (India), Sub-Zone Goa	CDSCO, Sub Zonal office, Goa
7	Mr. Virendra Singh	Drugs Inspector	CDSCO, Zonal office Ahmedabad
8	Mr. Ashok K Yadav	Drugs Inspector	CDSCO, Zonal office Ahmedabad
9	Mr. Milind P Patil	Drugs Inspector	CDSCO, Zonal office Ahmedabad
10	Mr. Kailash C. Meena	Drugs Inspector	CDSCO, Zonal office Ahmedabad
11	Mr. Ganesh J Nannaware	Drugs Inspector	CDSCO, Zonal office Ahmedabad
12	Mr. Neeraj Katiyar	Drugs Inspector	CDSCO, Zonal office Ahmedabad
13	Mr. V.K Panikar	Joint Commissioner	FDA, Maharashtra
14	Mr. G.K Vakhariya	Assistant Commissioner	FDA, Maharashtra
15	Dr. RakeshTripude	Assistant Commissioner	FDA, Maharashtra
16	Mr. S.B Patil	Drugs Inspector	FDA, Maharashtra

S. No	Name	Designation	Organization / Division
17	Mr. K.G Gadewar	Drugs Inspector	FDA, Maharashtra
18	Mr. J.B Mantri	Drugs Inspector	FDA, Maharashtra
19	Mr. Ajay Kumar jain	Drugs controller	Drugs Control Org. Rajasthan
20	Dr. Manoj Kumar Tripathi	Assistant Drugs Controller	Drugs Control Org. Rajasthan
21	Mr. Ajeet Jain	Drugs Control Officer	Drugs Control Org. Rajasthan
22	Mr. O.P .Yadav	Drugs Control Officer	Drugs Control Org. Rajasthan
23	Mr. Lalit Ajaria	Drugs Control Officer	Drugs Control Org. Rajasthan
24	Mr. Hemant Shrivasatava	Dy. Drugs Controller	FDA, Chhattisgarh
25	Mr. Sanjay Singh Jhadekar	Drugs Inspector	FDA, Chhattisgarh
26	Mr. Hiren M. Patel	Drugs Inspector	FDA, Chhattisgarh
27	Mrs C.U Chandrita	Sr. Drugs Inspector	FDCA, Gujarat
28	Mr. A.A Radadia	Sr. Drugs Inspector	FDCA, Gujarat
29	Mr. J.P Patel	Sr. Drugs Inspector	FDCA, Gujarat
30	Mr. N. R. Saiyad	Sr. Drugs Inspector	FDCA, Gujarat
31	Mr. J.A Patel	Sr. Drugs Inspector	FDCA, Gujarat
32	Mr. A.H Zala	Sr. Drugs Inspector	FDCA, Gujarat
33	Mr. V.P Solanki	Sr. Drugs Inspector	FDCA, Gujarat
34	Mr. C.R Mehta	Sr. Drugs Inspector	FDCA, Gujarat

S. No	Name	Designation	Organization / Division
35	Mr. R.M Patel	Sr. Drugs Inspector	FDCA, Gujarat
36	Mr. R.S Varanadani	Drugs Inspector	FDA , Madhya Pradesh
37	Mr. Rajneesh Choudhary	Drugs Inspector	FDA , Madhya Pradesh
38	Mr.DharmeshBigonia	Drugs Inspector	FDA , Madhya Pradesh
39	Mrs. Anumeda Vivek Kaushal	Drugs Inspector	FDA , Madhya Pradesh
40	Mr. P.P Singh	Assistant Commissioner(Drugs)	FDA Uttar Pradesh
41	Mr. P.K Modi	Assistant Commissioner(Drugs)	FDA Uttar Pradesh
42	Mr. Rajiv Bindal	Assistant Commissioner(Drugs)	FDA Uttar Pradesh
43	Mr. Anoop Kumar	Assistant Commissioner(Drugs)	FDA Uttar Pradesh
44	Mr. G. D Gaur	Assistant Commissioner(Drugs)	FDA Uttar Pradesh
45	Mr. Ramesh Kumar	Assistant Commissioner(Drugs)	States Drugs Control Department, Bihar
46	Mr.RakeshNandan Singh	Licensing Authority	States Drugs Control Department, Bihar
47	Mr. Girish J Vaghela	Drugs Inspector	Daman and Diu

- **Day-wise proceeding of the workshop is as follows:**
- **Day One – 01-02-2014**

  The agenda topics e.g. Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme, Existing GMP standards, their similarities and major differences (PIC/S, WHO, EU, US-FDA, Schedule M), Recent GMP developments and trends and Experience from WHO, PIC/S and Indian **API** inspections, most common problems and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) deliberated and discussed during the pre-lunch session. The agenda topics covered in the post lunch session were Good inspection practice, learning from recent cases with international implications, Co-operation and communication among inspectorates (moving from transparency to cooperation, to confidence building and reliance)

- **Day Two – 02-02-2014**
- The session was started with the agenda topic Experience from WHO, PIC/S and Indian inspections of oral solid dosage forms manufacturers - most common problem and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) followed by Inspection of the quality system (is the QS really in place or is it a requisite to satisfy inspectors formally) Quality risk management and how inspectors assess its implementation and how to assess plans of corrective actions and the change management up to the pre-lunch session. The post lunch session started with the presentation on HVAC systems and assessing risk of cross contamination followed by Management of out of specification results and Training of inspectors and ended up with the moderate discussion.

INTERACTIVE DISCUSSION DURING THE WORKSHOP

KNOWLEDGE SHARED BY INTERNATIONAL EXPERTS ON VARIOUS TOPICS

KNOWLEDGE SHARED BY INTERNATIONAL EXPERTS ON VARIOUS TOPICS

Part 3. : CDSCO–WHO Workshop for GMP strengthening of State Regulatory Inspectorate" on 4th -5th February, 2014 at Chandigarh

Introduction

The workshop was started with the opening address by Ms. Rubina Bose, Asst. Drugs Controller (I), CDSCO, HQ by welcoming dignitaries and introduction of all International experts to the participants. Ms. Rubina Bose thanked all the International Experts for joining the workshop to share their knowledge and explained background of the workshop and meticulous planning of the training in the form of lectures by experts. On behalf of CDSCO, Sub-zonal office Chandigarh Mr. Naresh Sharma, Assistant Drugs Controller (I), Chandigarh has welcomed all the experts and participants.

The Directorate has nominated 11 officers from different CDSCO Zones and Headquarter as participants, and 27 officers from different States.

INTRODUCTION OF INTERNATIONAL EXPERTS TO THE PARTICIPANTS

The list of participants is as per the table given below

S. No	Name	Designation	Organization / Division
1	Mrs Rubina Bose	Assistant Drugs Controller(India), (Head Quarter)	CDSCO, Head Quarter, New Delhi
2	Dr. K. Bangarurajan	Deputy Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
3	Mrs. Annam Visala,	Deputy Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
4	Dr. S.E. Reddy	Deputy Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
5	Mr. Sanjeev Kumar	Assistant Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
6	Dr. Ajay Sachan	Assistant Drugs Controller (India), North Zone	CDSCO, North Zone, Ghaziabad
7	Mr. Gulsan Taneja	Assistant Drugs Controller (India), Head Quarter	CDSCO, Head Quarter, New Delhi
8	Mr. Naresh Sharma	Assistant Drugs Controller (India), Sub-Zone Chandigarh	CDSCO, Sub Zonal office Chandigarh
9	Mr. Sushant Sharma	Drugs Inspector	CDSCO, Sub Zonal office Chandigarh
10	Mr. P. Manavalam	Drugs Inspector	CDSCO, Sub Zonal office Chandigarh
11	Mr. Munish Kakar	Drugs Inspector	CDSCO, Sub Zonal office Chandigarh
12	Dr. G.L. Singal	State Drugs Controller	Haryana
13	Mr. Raj Kumar	Deputy State Drugs Controller	Haryana

S. No	Name	Designation	Organization / Division
14	Mr.M.P. Gupta	Assistant State Drugs Controller	Haryana
15	Mr. N.K. Ahooja	Assistant State Drugs Controller	Haryana
16	Mr.Adarsh Goel	Assistant State Drugs Controller	Haryana
17	Mr. Ajay Singla	State Drugs Controlling & Licensing Authority	Punjab
18	Mr.Bhag Singh	Assistant Drugs Controller & Licensing Authority	Punjab
19	Ms. Neha Shoree	Drugs Inspector cum Zonal Licensing Authority	Punjab
20	Mr. Sanjiv Kumar Garg	Drugs Inspector cum Zonal Licensing Authority	Punjab
21	Mr.Pardeep Kumar	Assistant Drugs Controller & Licensing Authority	Punjab
22	Mr. Hemant Singh Negi	Sr. Inspector of Drugs	Uttarakhand
23	Mr.Tajber Singh	Inspector of Drugs	Uttarakhand
24	Mr.Deepak Kumar	Inspector of Drugs	Uttarakhand
25	Mr.Nazir Ahmad Wani	Dy.Controller- D.F.C.O	Jammu & Kashmir
26	Mr.Pervaiz Ahmad Bhat	Assistant Drugs Controller	Jammu & Kashmir
27	Mrs. Farida Parveen	Assistant Drugs Controller	Jammu & Kashmir

S. No	Name	Designation	Organization / Division
28	Mr. Munish Gupta	Assistant Drugs Controller	Jammu & Kashmir
29	Mrs. Lotika Khajuria	Dy.Controller	Jammu & Kashmir
30	Mr. K.T. Raghukumar	Drugs Inspector	Delhi
31	Mr.P. Arivazhagan	Drugs Inspector	Delhi
32	Mr.Navneet Marwaha	State Drugs Controller	Himachal Pradesh
33	Mr. R.K. Chaudhary	Assistant Drugs Controller cum Drugs Licensing Authority	Himachal Pradesh
34	Mr.Sunny Kaushal	Drugs Inspector cum Drugs Licensing Authority)	Himachal Pradesh
35	Mr.Kapil Dhiman	Drugs Inspector	Himachal Pradesh
36	Mr.Kamlesh Naik	Drugs Inspector	Himachal Pradesh
37	Mr.Nishant Sareen	Drugs Inspector cum Drugs Licensing Authority	Himachal Pradesh
38	Mr.Manish Kapoor	Drugs Inspector cum Drugs LicensinAuthority	Himachal Pradesh

- **Day-wise proceeding of the workshop is as follows:**
- **Day One – 04-02-2014**

  The agenda topics e.g. Position of Indian manufacturers in global supply of essential medicines and in WHO Prequalification of Medicines Scheme, Existing GMP standards, their similarities and major differences (PIC/S, WHO, EU, US-FDA, Schedule M), Recent GMP developments and trends and Experience from WHO, PIC/S and Indian **API** inspections, most common problems and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) deliberated and discussed during the pre-lunch session. The agenda topics covered in the post lunch session were Good inspection practice, learning from recent cases with international implications, Co-operation and communication among inspectorates (moving from transparency to cooperation, to confidence building and reliance)

- **Day Two – 05-02-2014**
- The session was started with the agenda topic Experience from WHO, PIC/S and Indian inspections of oral solid dosage forms manufacturers - most common problem and regional issues (comparing individual experience, discussion on inspection approaches and conclusions, remedial actions) followed by Inspection of the quality system (is the QS really in place or is it a requisite to satisfy inspectors formally) Quality risk management and how inspectors assess its implementation and how to assess plans of corrective actions and the change management up to the pre-lunch session. The post lunch session started with the presentation on HVAC systems and assessing risk of cross contamination followed by Management of out of specification results and Training of inspectors and ended up with the moderate discussion.

PARTICIPANTS TAKING KEEN INTEREST DURING THE PRESENTATION

INTERACTIVE DISCUSSION DURING THE WORKSHOP

GROUP PHOTOGRAPH DURING CLOSING CEREMONY AT CHANDIGARH

OUTCOME:

- Knowledge on Adaptive regulations and guidance to emerging threats
- Knowledge on convergence of interpretation of what the GMPs actually mean
- Awareness on Recent development of GMP Standards
- Discussed and understood why implementation of a quality system helps achieve compliance with current GMP.
- Imparted knowledge on how to prepare plan of individual GMP inspection
- Detailed training in planning, preparing, conducting GMP inspection with specific emphasis to API and OSD facilities and dealing with serious non-compliance, data fraud, false or misleading information