

# Workshop on “Basic Good Clinical Practices (GCP)” for Officers of Central & State Drugs Control Organization

10<sup>th</sup> -11<sup>th</sup> March, 2014



Workshop on “Basic Good Clinical Practices (GCP)” for officers of Central & State Drug Control Organization was organized by Quality Assurance Division of Central Drugs Standard Control Organization (CDSCO) on 10<sup>th</sup> - 11<sup>th</sup> March, 2014 to increase the capacity and knowledge of the reviewers and Inspectors of CDSCO in regulatory oversight of clinical trials including GCP Inspections and Ethical Issues in Clinical Trials in India to implement effective Regulatory Oversight.

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# **Objective of the Workshop**

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To improve the reviewing and inspection skills of the Drugs Inspectors of central and State in regulatory oversight of clinical trials including GCP Inspections and Ethical Issues in Clinical Trials in India as a part of capacity building of the Indian Regulatory System.

## Agenda of the Workshop

10<sup>th</sup> March, 2014

Time	Topic	Speaker
9:00 - 9:30	Registration	-
9:30 - 10:00	Inaugural session (Welcome address, Introduction of workshop and participants)	CDSCO
10:00 – 10:15	Pre-Assessment	CDSCO
10:15 – 10:30	<b>Tea Break</b>	
10:30 - 11:30	Impact of recent Regulatory Changes For Conducting Clinical Trial In India	CDSCO
11:30 – 12:00	Discussion	Participants
12:00 – 12:45	Clinical Trial Inspection in India	Dr. Y.K Gupta, Prof and HOD, Department of Pharmacology AIIMS
12:45 – 13:30	<b>Lunch Break</b>	
13:30 – 14:00	Preparation For Site Visit	Participants and Facilitators from CDSCO
14:00-18-00	Site Visit	All Participants and Facilitators

**11<sup>th</sup> March, 2014**

<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
10:00 – 10:30	Impact of recent Regulatory Changes for Conducting Clinical Trial in India- cont.	CDSCO
10:30-10:45	<b>Tea Break</b>	
10:45-13:00	Report Preparation and Presentation	All Participants
13:00 – 14:00	<b>Lunch Break</b>	
14:00 – 15:15	Clinical trial inspection Checklist & common observations	Mrs. Annam Visala, DDC (I)
15:15 – 15:45	Discussion	Participants
15:45 – 16:00	<b>Tea Break</b>	
16:00 – 17:00	Open discussion on visit and inspection checklist	
17:00 – 17:15	Post Assessment	CDSCO
17:15-17:30	Valedictory session	CDSCO

**List of Participants**  
**10th and 11th March, 2014**

<b>S. No.</b>	<b>Name</b>	<b>Designation</b>	<b>Organization</b>
<b>Experts</b>			
1	Dr. Y.K. Gupta	Professor & Head	AIIMS, New Delhi
<b>Facilitators</b>			
2	Ms. Annam Visala	Deputy Drugs Controller (India)	CDSCO (HQ)
3	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO (HQ)
4	Ms. Rubina Bose	Assistant Drugs Controller (India)	CDSCO (HQ)
5	Ms. Swati Srivastava	Assistant Drugs Controller (India)	CDSCO (HQ)
6	Mr. Somnath Basu	Assistant Drugs Controller (India)	CDSCO (HQ)
7	Mr. Gaurav Kumar	Assistant Drugs Controller (India)	CDSCO (HQ)
8	Mr. Sunil Kulshrestha	Assistant Drugs Controller (India)	CDSCO (HQ)
9	Dr. Ravi Kant Sharma	Assistant Drugs Controller (India)	CDSCO (HQ)

### List of Participants from CDSCO

10	Mr. Saurabh Garg	Drugs Inspector	CDSCO (HQ)
11	Mr. Sourabh Mittal	Drugs Inspector	CDSCO (HQ)
12	Mr. Devendra Nath	Drugs Inspector	CDSCO (HQ)
13	Mr . Rakesh Negi	Drugs Inspector	CDSCO (HQ)
14	Mr. Amol Eknath Kandekar	Drugs Inspector	CDSCO (HQ)
15	Mr. Rahul Panwar	Drugs Inspector	CDSCO (HQ)
16	Mr. Ankur Bansal	Drugs Inspector	CDSCO (HQ)
17	Mr. Fahim Khan	Drugs Inspector	CDSCO (HQ)
18	Mr. Sachin Yadaorao Bhagwate	Drugs Inspector	CDSCO (HQ)
19	Mr. Sri Babu	Drugs Inspector	CDSCO (HQ)
20	Mr. Deepak Kumar Sehrawat	Drugs Inspector	CDSCO (HQ)
21	Mr. Baljeet Singh	Drugs Inspector	CDSCO (HQ)
22	Mr. Dinesh Kumar	Drugs Inspector	CDSCO (HQ)
23	Mr. Popat Dattatraya Thorat	Drugs Inspector	CDSCO (HQ)
24	Mr. Manoj Choudhary Jatav	Drugs Inspector	CDSCO (HQ)
25	Mr. Pratyush Kumar	Drugs Inspector	CDSCO (HQ)

26	Mr. Arvind Singh Panwar	Drugs Inspector	CDSCO (HQ)
27	Dr. Vijai Singh Karwasara	Drugs Inspector	CDSCO (HQ)
28	Mr. Dileep Kumar	Drugs Inspector	CDSCO (HQ)
29	Ms. Suniti Choudhary	Drugs Inspector	CDSCO (HQ)
30	Ms. Nisha Kaushik	Drugs Inspector	CDSCO (HQ)
31	Mr. Saurabh Jain	Drugs Inspector	CDSCO (HQ)
32	Mr. Pushpraj Kumar Singh	Drugs Inspector	CDSCO (HQ)
33	Mr. Surender Kumar Kaswan	Drugs Inspector	CDSCO (HQ)
34	Mr. Sandeep Kumar	Drugs Inspector	CDSCO (HQ)
35	Mr. Rahul Singh	Drugs Inspector	CDSCO (HQ)
36	Mr. Abhinav Kapoor	Drugs Inspector	CDSCO (HQ)
37	Mr. Akash Rama Kondalkar	Drugs Inspector	CDSCO (HQ)
38	Mr. Munish Kakar	Drugs Inspector	Chandigarh
39	Mr. Arun Kumar Prashar	Drugs Inspector	Jammu
40	Mr. Kailash Chander Malik	Drugs Inspector	East Zone
41	Mr. Bikramaditya Chowdhury	Drugs Inspector	CDSCO (HQ)
42	Dr. Bikash Roy	Drugs Inspector	CDSCO (HQ)
43	Mr. Manish Horo	Drugs Inspector	CDSCO (HQ)
44	Ms. Kiran Singh	Drugs Inspector	CDSCO (HQ)
45	Mr. Bibekananda Behera	Drugs Inspector	CDSCO (HQ)
46	Mr. Shabeer Ashfaque Abdulla	Drugs Inspector	CDSCO (HQ)

## List of Participants from States

47	Mr. Sushen Mazumder	Drugs Inspector	Assam
48	Ms. Shail Ambastha	Drugs Inspector	Jharkhand

- After registration of all the participants, Ms. Rubina Bose, Assistant Drugs Controller (India), CDSCO welcomed all the experts and the participants and also gave brief introduction to the workshop.
- Dr. A. Ramkishan, Deputy Drugs Controller (India), CDSCO addressed the importance of this workshop and highlighted the mandate, mission and vision of CDSCO, objective and expectation from this workshop. He also discussed on the topic “Impact of recent Regulatory Changes for Conducting Clinical Trial in India”.



**Official Inauguration and welcome address of the workshop was made by Ms. Rubina Bose, Assistant Drugs Controller (India)**



**Objective and expectation of the workshop was explained by Dr. A. Ramkishan, Deputy Drugs Controller (India), CDSCO addressing participants**



**Dr. Y.K.Gupta**, gave presentation on **“Clinical Trial Inspection”**. In his presentation he discussed Do’s and Don’ts of inspection. He also elaborated and discussed the various observations made by different regulatory agencies during clinical trial inspections.

**Dr. Y.K. Gupta**  
**Professor & Head, AIIMS**



Ms. Annam Visala, gave presentation on **“Clinical trial inspection Checklist & common observations”**.

She also discussed about the importance of writing good inspection reports and how to write good inspection report.

**Ms. Annam Visala  
Deputy Drugs Controller (India)**



**Participants during the Pre-Assessment and Post-Assessment**



**Participants from State and CDSCO took keen interest during the Presentations**



**Facilitators along with Participants took keen interest during the Presentations**



**Ms. Swati Srivastava, Assistant Drugs Controller (India) guiding her group during preparation of presentation**

# Groups preparing their presentation on the observations during the Site Visit





**Groups presenting their observations of Site Visit**



**Groups presenting their observations of Site Visit**



**Groups presenting their observations of Site Visit**



**Dr. A. Ramkishan, DDC(I) giving his comments on the observations of the various groups**



**Group Photograph during closing ceremony of the workshop**