

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

12<sup>th</sup> -14<sup>th</sup> March, 2014



As a part of NRA strengthening activities and capacity building, Central Drugs Standard Control Organization (CDSCO) had recruited large number of Drugs Inspectors. The Drugs Inspectors appointed in CDSCO have duties and responsibilities to discharge the functions under Drugs & Cosmetic Act and Rules and other job responsibilities such as inspections for certification of Pharmaceutical products as per WHO norms, inspection for licensing of biological products, large volume Parenterals and review of dossier submitted for the marketing authorization etc.

CDSCO has planned and completed “**Three days workshop on Advanced Good Clinical Practices (GCP)**” at **Hotel Metropolitan, Bangla Sahib Road, New Delhi** from 12<sup>th</sup> to 14<sup>th</sup> March 2014.

# **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

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

<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
9:30 - 10:00	Registration	-
10:00 - 10:30	Inaugural session (Welcome address, Introduction of workshop and participants)	CDSCO
10:30 - 10:45	Pre-Assessment	CDSCO
10:45 - 11:00	<b>Tea Break</b>	
11:00 - 12:00	Challenges in Clinical trial inspections in India	Dr. Y. K Gupta
12:00 - 13:00	Preparation for mock audit	Participants
13:00 - 14:00	<b>Lunch Break</b>	
14:00 - 15:00	Preparation for mock audit	All participants
15:00 - 16:00	Clinical trial inspection Checklist & common observations	Ms. A. Visala
16:00 - 16:15	<b>Tea Break</b>	
16:15 - 17:30	Preparation for the Mock Audit	Participants

## 13<sup>th</sup> March, 2014

<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
10:00 – 18:00	Mock Audit at Clinical Trial Sites	All participants and facilitators from CDSCO

## 14<sup>th</sup> March, 2014

<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
10:00 – 11:00	Keynote Address on Clinical Trial	Dr. A.K. Aggarwal
11:00 – 11:15	<b>Tea Break</b>	
11:15 - 13:00	Report compilation of Mock Audit	Participants
13:00 – 14:00	<b>Lunch Break</b>	
14:00 – 15:45	Report compilation of Mock Audit	Participants
15:45 – 16:00	<b>Tea Break</b>	
16:00 – 16:45	Report compilation of Mock Audit	Participants
16:45 – 17:15	Presentation of inspection Report	Participants
17:15 – 17:30	Post Assessment	CDSCO

## List of Participants: - 12<sup>th</sup>- 14<sup>th</sup> March, 2014

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

## List of Participants from CDSCO

11	Mr. Manish Singhal	Drugs Inspector	CDSCO (HQ)
12	Mr. Vinod Kumar	Drugs Inspector	CDSCO (HQ)
13	Ms. Nisha Sankhwar	Drugs Inspector	CDSCO (HQ)
14	Mr. Sella Senthil M	Drugs Inspector	CDSCO (HQ)
15	Mr. Yogesh Shelar	Drugs Inspector	CDSCO (HQ)
16	Mr. Shashi Paul	Drugs Inspector	CDSCO (HQ)
17	Mr. P.Manavalan	Drugs Inspector	Chandigarh
18	Mr. Sanjay Kumar Agrawal	Drugs Inspector	CDSCO (HQ)
19	Mr. Suresh Kumar Kalwaniya	Drugs Inspector	CDSCO (HQ)
20	Mr. Dharmvir Singh	Drugs Inspector	CDSCO (HQ)
21	Mr. Sushant Sharma	Drugs Inspector	Chandigarh
22	Ms. Bharti Bachloo	Drugs Inspector	Jammu
23	Mr. Rajesh Kumar Verma	Drugs Inspector	CDSCO (HQ)
24	Mr. Ashish Kumar Rai	Drugs Inspector	CDSCO (HQ)
25	Mr. Vinay Kumar Gupta	Drugs Inspector	CDSCO (HQ)
26	Mr. S. John Gerard	Drugs Inspector	CDSCO (HQ)

27	Mr. Sushanta Sarkar	Drugs Inspector	CDSCO (HQ)
28	Mr. C. Manivillavan	Drugs Inspector	CDSCO (HQ)
29	Mr. C. Arunachalam	Drugs Inspector	CDSCO (HQ)
30	Mr. Sidharth Sahai Malhotra	Drugs Inspector	CDSCO (HQ)
31	Mr. Mukesh Kumar	Drugs Inspector	CDSCO (HQ)
<b>List of Participants from States</b>			
32	Mr. Biswajit Das Gupta	Drugs Inspector	Bihar
33	Ms. Neha Shoree	Zonal Licensing Authority	Punjab
34	Mr. Man Mohan Taneja	Senior Drugs Control Officer	Haryana
35	Mr. Kanahaiyalal Agarwal	Drugs Inspector	Madhya Pradesh

- 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.
- This was followed by pre-assessment and subsequent address to the participants by Dr. A. Ramkishan, Deputy Drugs Controller (India), CDSCO on the importance of this workshop.



**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.



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)**



**Dr. A.K. Aggarwal,**  
explained about the  
development and  
history of Clinical  
research in India.



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



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



**Facilitators along with participants during the Presentations**



**Facilitators along with participants during the Presentations**



**Facilitators along with participants during the Presentations**



**Groups presenting their observations of Mock Audit**



**Groups presenting their observations of Mock Audit**



**Groups presenting their observations of Mock Audit**



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