



**WORKSHOP ON “DESIGN, REVIEW OF CLINICAL  
TRIAL PROTOCOL AND ROLE OF BIO-  
STATISTICIANS”**

**FOR**

**OFFICERS OF CENTRAL DRUGS  
STANDARD CONTROL ORGANIZATION  
ON**

**22<sup>nd</sup> -24<sup>th</sup> JANUARY, 2014**

The workshop on “**Design, Review of Clinical Trial Protocol and Role of Bio-statisticians**” was organized by Quality Assurance Division of CDSCO at Hotel Metropolitan, Bangla Sahib Road, New Delhi on 22<sup>nd</sup> -24<sup>th</sup> January, 2014 to impart the knowledge on review of Clinical Trial Protocol to Officers of Central Drugs Standard Control Organization.

The workshop on “**Design Review of Clinical Trial Protocol and Role of Bio-statisticians**” was organized for three days, the first two days 22<sup>nd</sup> -23<sup>rd</sup> January, 2014 was planned for the Drugs Inspectors who review clinical trial protocols, alongwith ADC(I) and DDC(I) of the concerned divisions. The third day i.e. 24<sup>th</sup> January, 2014 was planned for the Drugs Inspectors who review vaccine clinical trial protocols, alongwith ADC (I) and DDC (I) of the concerned divisions.

Experts from Central Drugs Research Institute (CDRI), Luck now, All India Institute of Medical Science (AIIMS) and Maulana Azad Medical College (MAMC) gave the presentations to all the participants.

The objective of this workshop was to strengthen the Regulatory System on Clinical Trials. Regulatory oversight of Clinical Trial and Marketing Authorization and Licensing are two functional indicators. To fulfill the indicators it is required to increase the capacity and knowledge of the reviewers of CDSCO in Clinical Trial Protocol, Ethical oversight and role of Bio-statisticians in Clinical Studies including its evaluation.

# Agenda for the workshop

22 January, 2014

TIME	TITLE OF ACTIVITY	SPEAKER/ PARTICIPANTS
09:00 am – 09.30 am	Registration	
09:30 am – 09:45 am	Inaugural Session (Welcome address, Introduction of participants)	CDSCO
9:45am - 10:00am	Pre-assessment	
10:00am - 10:30 am	Role of Biostatistician in review of Clinical Trial protocol and report	Mrs. M. Kalaivani, Scientist-III ,AIIMS, New Delhi
10:30am - 10:45am	Tea Break	
10:45am - 11:15am	Case Study	Mrs. M. Kalaivani, Scientist-III ,AIIMS, New Delhi and all participants
11:15am - 11:30pm	Group Discussion	-do-
11:30pm - 12:15pm	Design & Review of Clinical trial protocol (including method of randomization)and Clinical trial report	Dr. Vivek Bhosale, Scientist, CDRI, Lucknow
12:15pm - 12:45pm	Case Study	Dr. Vivek Bhosale, Scientist,CDRI,

TIME	TITLE OF ACTIVITY	SPEAKER/ PARTICIPANTS
12:45pm - 1:00pm	Group Discussion	-do-
1:00pm - 1:45pm	Lunch Break	
1:45pm - 2:30pm	Drug Design & Development, Pre-formulation Studies up to Scale-up.	Dr. Anil Kumar Saxena, Chief Scientist & Former Head, CDRI, Luck now
2:30pm - 3:00pm	Case Study	-do-
3:00pm - 3:15pm	Group Discussion	-do-
3:15pm - 3:30pm	Tea Break	
3:30pm - 4:15pm	Pre-clinical safety evaluation (Safety, pharmacology & toxicology studies) as per regulatory requirements	Dr. Anil Kumar Saxena, Chief Scientist & Former Head, CDRI, Luck now
4:15pm - 4:45pm	Case Study	-do-
4:45pm - 5:00pm	Group Discussion	-do-
5:00pm - 5:15pm	Post-assessment	CDSCO

# AGENDA FOR THE WORKSHOP

## 23 JANUARY, 2014

TIME	TITLE OF ACTIVITY	SPEAKER/ PARTICIPANTS
09:00 am – 09.30 am	Registration	
09:30 am – 09:45 am	Pre-assessment	CDSCO
9:45am - 10:30am	Drug Design & Development, Pre-formulation Studies up to Scale-up"	Dr. Anil Kumar Saxena, Ex. Chief Scientist & Former Head, CDRI, Luck now
10:30am - 10:45 am	Tea Break	
10:45am - 11:15am	Case Study	Dr. Anil Kumar Saxena, Ex. Chief Scientist & Former Head, CDRI, Luck now and all the participants
11:15am - 11:30pm	Group Discussion	-do-
11:30pm - 12:15pm	Pre-clinical safety evaluation (Safety, pharmacology & toxicology studies) as per regulatory requirements.	Dr. Anil Kumar Saxena, Ex. Chief Scientist & Former Head, CDRI, Luck now
12:15pm - 12:45pm	Case Study	Dr. Anil Kumar Saxena, Ex. Chief Scientist & Former Head, CDRI, Luck now and all the participants
12:45pm – 1:00pm	Group Discussion	-do-

# AGENDA FOR THE WORKSHOP

TIME	TITLE OF ACTIVITY	SPEAKER/ PARTICIPANTS
1:00pm - 1:45pm	Lunch Break	
1:45pm - 2:30pm	Design & Review of Clinical trial protocol (including method of randomization) and Clinical trial report".	Dr. Vivek Bhosale, Scientist, CDRI ,Lucknow
2:30pm - 3:00pm	Case study	Dr. Vivek Bhosale, Scientist, CDRI ,Lucknow and all participants
3:00pm - 3:15pm	Group Discussion	-do-
3:15pm - 3:30pm	Tea Break	
3:30pm - 4:15pm	Role of Biostatistician in review of Clinical Trial protocol and report	Mrs. M. Kalaivani, Scientist-III ,AIIMS, New Delhi
4:15pm - 4:45pm	Case study	Mrs. M. Kalaivani, Scientist-III ,AIIMS, New Delhi and all participants
4:45pm - 5:00pm	Group Discussion	-do-
5:00 pm - 5:15pm	Post-assessment	CDSCO

# AGENDA FOR THE WORKSHOP

## 24 JANUARY, 2014

TIME	TITLE OF ACTIVITY	SPEAKER/ PARTICIPANTS
10:00am - 10:30 am	Present Regulatory Regime in Clinical Trials	CDSCO
10:30am - 10:45am	Tea Break	
10:45am -11:45am	Present Regulatory Regime in Clinical Trials	CDSCO
11:45am - 1:00pm	Regulatory requirements in clinical Trials- specific to Biological Products	CDSCO
1:00pm - 1:45pm	Lunch Break	
1:45pm - 2:30pm	Review of clinical trial protocol and report of vaccines- salient features	Dr. Sangeeta Yadav, Professor, MAMC
2:30pm -3:00pm	Case study	Dr. Sangeeta Yadav, Professor, MAMC and all participants
3:00pm - 3:15pm	Group Discussion	-do-
3:15pm - 3:30pm	Tea Break	

# AGENDA FOR THE WORKSHOP

<b>TIME</b>	<b>TITLE OF ACTIVITY</b>	<b>SPEAKER/ PARTICIPANTS</b>
1:45pm - 2:30pm	Review of clinical trial protocol and report of vaccines- salient features	Dr. Sangeeta Yadav, Professor, MAMC
2:30pm -3:00pm	Case study	Dr. Sangeeta Yadav, Professor, MAMC and all participants
3:00pm - 3:15pm	Group Discussion	-do-
3:15pm - 3:30pm	Tea Break	
3:30pm - 4:45pm	Case study on role of Biostatistician in review of Clinical Trial protocol and report of vaccine	Mrs. M. Kalaivani, Scientist-III ,AIIMS, New Delhi and all participants
4:45pm - 5:00pm	Group Discussion	-do-

# List of Participants on 22 January, 2014

Sr. No.	Name of the Participant	Office Address	Designation
1.	Dr. A. K. Saxena	CDRI, Lucknow	Ex. Chief Scientist & Former Head
2.	Dr. Vivek Bhosale	CDRI, Lucknow	Scientist
3.	Dr. M. Kalaivani	AIIMS, New Delhi	Scientist-III
4.	Dr. A. Ramkishan	CDSCO (HQ)	Deputy Drugs Controller(I)
5.	Mr. S.P. Shani	CDSCO, HQ	Deputy Drugs Controller(I)
6.	Mr. S.P. Shani	CDSCO, HQ	Deputy Drugs Controller (I)
7.	Smt. Annam Visala	CDSCO, HQ	Deputy Drugs Controller (I)
8.	Dr. Inderjeet Singh Hura	CDSCO, HQ	Assistant Drugs Controller (India)
9.	Mrs. Rubina Bose	CDSCO, HQ	Assistant Drugs Controller (I)

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
10.	Ms. Swati Srivastava	CDSCO, HQ	Assistant Drugs Controller (I)
11.	Mr. Vinay Kumar Gupta	CDSCO, HQ	Drugs Inspector
12.	Mr. Milind Patil	CDSCO, Ahmedabad	Drugs Inspector
13.	Mr. Vinod Kumar	CDSCO, HQ	Drugs Inspector
14.	Mr. Sourabh Mittal	CDSCO, HQ	Drugs Inspector
15.	Dr. Vijay Kumar Karwasra	CDSCO, HQ	Drugs Inspector
16.	Ms. A. Ambuselvi	CDSCO, HQ	Drugs Inspector
17.	Mr. Bidhyashekhar	CDSCO, HQ	Drugs Inspector
18.	Mr. Arvind Singh Panwar	CDSCO, HQ	Drugs Inspector
19.	Ms. Sunitha Seerapu	CDSCO, HQ	Drugs Inspector
20.	Mr. Pratyush Kumar	CDSCO, HQ	Drugs Inspector
21.	Mr. Parthiban J.	CDSCO, HQ	Drugs Inspector
22.	Mr. Deepak Kumar Sehrawat	CDSCO, HQ	Drugs Inspector

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
23.	Mr. Amol Eknath Kandekar	CDSCO, HQ	Drugs Inspector
24.	Mr. Popat Dattaraya Thorat	CDSCO, HQ	Drugs Inspector
25.	Ms. Shyamaladevi D.	CDSCO, HQ	Drugs Inspector
26.	Mr. Manish Horo	CDSCO, HQ	Drugs Inspector
27.	Mr. Avinash Kumar Yadav	CDSCO, HQ	Drugs Inspector
28.	Ms. Nisha Kaushik	CDSCO, HQ	Drugs Inspector
29.	Mr. V. Sooraj	CDSCO, HQ	Drugs Inspector
30.	Mr. Sandeep Kumar	CDSCO, HQ	Drugs Inspector
31.	Mr. Abhinav Kapoor	CDSCO, HQ	Drugs Inspector
32.	Mr. Bikramaditya Chowdhury	CDSCO, HQ	Drugs Inspector
33.	Mr. Balakumar Mahalingam	CDSCO, HQ	Drugs Inspector

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
34.	Dr. Bikash Roy	CDSCO, HQ	Drugs Inspector
35.	Mr. John G.	CDSCO, HQ	Drugs Inspector
36.	Mr. C. Arunachalam	CDSCO, HQ	Drugs Inspector
37.	Mr. Manish Nikhra	CDSCO, EZ	Drugs Inspector
38.	Mr. Dinesh Kumar	CDSCO, NZ	Drugs Inspector
39.	Ms. Prerna Saurabh	CDSCO, HQ	Technical Data Associate
40.	Ms. Vandana Wallabh	CDSCO, HQ	Technical Data Associate
41.	Ms. Swarupa Wankhade	CDSCO, HQ	Technical Data Associate
42.	Ms. Shraddha Mishra	CDSCO, HQ	Technical Data Associate
43.	Ms. Barkha Dubey	CDSCO, HQ	Technical Data Associate
44.	Mr. Mohd. Fayyaz Rashid	CDSCO, HQ	Technical Data Associate
45.	Ms. Pooja Arora	CDSCO, HQ	Technical Data Associate
46.	Mr. A. J. Singh	CDSCO, HQ	Technical Data Associate

# List of Participants on 23 January, 2014 .

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
1.	Dr. A. K. Saxena	CDRI, Lucknow	Chief Scientist & Former Head
2.	Dr. Vivek Bhosale	CDRI, Lucknow	Scientist
3.	Dr. M. Kalaivani	AIIMS, New Delhi	Scientist-III
4.	Dr. A. Ramkishan	CDSCO (HQ)	Deputy Drugs Controller(I)
5.	Mr. S.P. Shani	CDSCO, HQ	Deputy Drugs Controller (I)
6.	Dr. Inderjeet Singh Hura	CDSCO, HQ	Assistant Drugs Controller (India)
7.	Mr. Somnath Basu	CDSCO, HQ	Assistant Drugs Controller (I)
8.	Mrs. Rubina Bose	CDSCO, HQ	Assistant Drugs Controller (I)
9.	Ms. Swati Srivastava	CDSCO, HQ	Assistant Drugs Controller (I)

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
10.	Mr. Yogesh Shelar	CDSCO, HQ	Drugs Inspector
11.	Mr. Rajesh Kumar Verma	CDSCO, HQ	Drugs Inspector
12.	Mr. Vinod Kumar	CDSCO, HQ	Drugs Inspector
13.	Mr. Ankur Bansal	CDSCO, HQ	Drugs Inspector
14.	Mr. Rahul Panwar	CDSCO, HQ	Drugs Inspector
15.	Mr. Fahim Khan	CDSCO, HQ	Drugs Inspector
16.	Mr. Hemant Madhukar Patil	CDSCO, HQ	Drugs Inspector
17.	Ms. Sudarmathi S.	CDSCO, HQ	Drugs Inspector
18.	Mr. Manoj Choudhary Jatav	CDSCO, HQ	Drugs Inspector
19.	Mr. Rakesh Negi	CDSCO, HQ	Drugs Inspector
20.	Mr. Amol Eknath Kandekar	CDSCO, HQ	Drugs Inspector
21.	Mr. Sachin Yadaorao Bhagwate	CDSCO, HQ	Drugs Inspector
22.	Mr. Sri Babu	CDSCO, HQ	Drugs Inspector

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
23.	Mr. Bibekananda Behera	CDSCO, HQ	Drugs Inspector
24.	Mr. Dinesh Kumar	CDSCO, HQ	Drugs Inspector
25.	Mr. Sunil Kumar Malviya	CDSCO, HQ	Drugs Inspector
26.	Mr. Dileep Kumar	CDSCO, HQ	Drugs Inspector
27.	Mr. Basant Kumar Yadav	CDSCO, HQ	Drugs Inspector
28.	Mr. Saurabh Jain	CDSCO, HQ	Drugs Inspector
29.	Mr. Haribabu J.	CDSCO, HQ	Drugs Inspector
30.	Mr. Jay Jyoti Roy	CDSCO, HQ	Drugs Inspector
31.	Mr. Akash Rama Kondalkar	CDSCO, HQ	Drugs Inspector
32.	Mr. S.R. Manikandan	CDSCO, HQ	Drugs Inspector
33.	Mr. J. Suresh kumar	CDSCO, HQ	Drugs Inspector

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
34.	Ms. C.Thiruvudha	CDSCO, HQ	Drugs Inspector
35.	Mr. Mohan R.	CDSCO, HQ	Drugs Inspector
36.	Mr. Dhananjay Sable	CDSCO, HQ	Drugs Inspector
37.	Saurabh Garg	CDSCO, HQ	Drugs Inspector
38.	Ms. Purna Saurabh	CDSCO, HQ	Technical Data Associate
39.	Ms. Pragya Sharma	CDSCO, HQ	Technical Data Associate
40.	Haris Chandran. S	CDSCO, HQ	Technical Data Associate

# List of Participants on 24 January, 2014

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
1	Dr. Sangeeta Yadav,	MAMC, New Delhi	Professor
2	Dr. M. Kalaivani	AIIMS, New Delhi	Scientist II
3	Mr. S.P. Shani	CDSCO, HQ	Deputy Drugs Controller (I)
4	Ms. Rubina Bose	CDSCO, HQ	Assistant Drugs Controller (I)
5	Ms. Swati Srivastava	CDSCO, HQ	Assistant Drugs Controller (I)
6	Mr. I.S. Hura	CDSCO, HQ	Assistant Drugs Controller (I)
7	Mr. Jayant Gangakhedkar	CDSCO, HQ	Assistant Drugs Controller (I)
8	Mr. Saurabh Garg	CDSCO, HQ	Drugs Inspector
9	Mr. Sourabh Mittal	CDSCO, HQ	Drugs Inspector
10	Mr. Devendra Nath	CDSCO, HQ	Drugs Inspector
11	Mr. Rakesh Negi	CDSCO, HQ	Drugs Inspector
12	Mr. Amol Eknath Kandekar	CDSCO, HQ	Drugs Inspector
13	Mr. Ankur Bansal	CDSCO, HQ	Drugs Inspector
14	Mr. Fahim Khan	CDSCO, HQ	Drugs Inspector
15	Mr. Rahul Panwar	CDSCO, HQ	Drugs Inspector

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
16	Mr. Rajesh Verma	CDSCO, HQ	Drugs Inspector
17	Mr. Vinod Kumar	CDSCO, HQ	Drugs Inspector
18	Mr. Pushpraj Kumar Singh	CDSCO, HQ	Drugs Inspector
19	Ms. A Anbuselvi	CDSCO, HQ	Drugs Inspector
20	Mr. Bidya Sekhar Mishra	CDSCO, HQ	Drugs Inspector
21	Mr. Hemant Madhukar Patil	CDSCO, HQ	Drugs Inspector
22	Mr. Arvind Singh Panwar	CDSCO, HQ	Drugs Inspector
23	Dr. Vijai Singh Karwasara	CDSCO, HQ	Drugs Inspector
24	Mr. Surender Kumar Kaswan	CDSCO, HQ	Drugs Inspector
25	Mr. Sandeep Kumar	CDSCO, HQ	Drugs Inspector
26	Mr. Jay Jyoti Roy	CDSCO, HQ	Drugs Inspector
27	Sh. A. K. Rai	CDSCO, HQ	Drugs Inspector
28	Mr. Sanjay Kr. Agrawal	CDSCO, HQ	Drugs Inspector
29	Mr. Sushant Sarkar	CDSCO, HQ	Drugs Inspector
30	Mr. John Gerard	CDSCO, HQ	Drugs Inspector

<b>Sr. No.</b>	<b>Name of the Participant</b>	<b>Office Address</b>	<b>Designation</b>
31	Mr. Manish Singhal	CDSCO, HQ	Drugs Inspector
32	Mr. Vinay Kumar	CDSCO, HQ	Drugs Inspector
33	Mr. Dharmvir Singh	CDSCO, HQ	Drugs Inspector
34	Ms. SunithaSeerapu	CDSCO, HQ	Drugs Inspector
35	Mr. Manoj Choudhary Jatav	CDSCO, HQ	Drugs Inspector
36	Ms. S. Sudarmathi	CDSCO, HQ	Drugs Inspector
37	Rahul Singh	CDSCO, HQ	Drugs Inspector
38	Mukesh Kumar	CDSCO, HQ	Drugs Inspector
39	Ms. Prerna Saurabh	CDSCO, HQ	Technical Data Associate
40	Ms. Vandana	CDSCO, HQ	Technical Data Associate
41	Ms. Swarupa A. Wankhade	CDSCO, HQ	Technical Data Associate
42	Ms. Pragya Sharma	CDSCO, HQ	Technical Data Associate



**‘Workshop on “Design & Review of Clinical Trial Protocol and Role of Bio-Statisticians”**

**for Officers of**

**Central Drugs Standard Control Organization**

**22<sup>nd</sup>-24<sup>th</sup> January, 2014**

**Venue: Hotel Metropolitan, Bangla Sahib Road, New Delhi - 110001**



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

- ✘ After registration of all the participants and facilitators, Mrs. Rubina Bose, Assistant Drugs Controller (India), CDSCO welcomed all the experts and the participants and also explained the procedure of the workshop.
- ✘ Dr. A. Ramkishan, Deputy Drugs Controller (India) has chaired the session and emphasized on significance of development of good Protocols in Clinical Research and also briefed about the review procedures during the workshop.
- ✘ Preassessment and post assessment was also part of agenda for evolution of knowledge of the participants on the subject.
- ✘ The experts from Central Drugs Research Institute (CDRI) Mr. A.K. Saxena, Chief Scientist & Former Head, CDRI, Lucknow, delivered presentations on Drug Design & Development, Pre-formulation Studies up to Scale-up" and Pre-clinical safety evaluation (Safety, pharmacology & toxicology studies) as per regulatory requirements. Also Dr. Vivek Bhosale, Scientist, CDRI, Lucknow discussed the Design & Review of Clinical trial protocol (including method of randomization) and Clinical trial report.
- ✘ The case study and group discussion of individual topic imparted practical knowledge to all the participants.
- ✘ Dr. M. Kalaivani, Scientist-III, and Biostatistician, AIIMS, New Delhi gave presentation on Role of Biostatistician in review of Clinical Trial protocol and report along with case studies to all the participants.
- ✘ Dr. Sangeeta Yadav, Professor, MAMC, delivered presentation on Review of clinical trial protocol and report of vaccines- salient features to all the participants.



Dr. A. Ramkishan, Deputy Drugs Controller (India) has chaired the session and emphasized on significance of development of good Protocols in Clinical Research and also briefed about the review procedures during the workshop.



**PRE - ASSESSMENT OF THE PARTICIPANTS**



Dr. A.K. Saxena, Chief Scientist from CDRI Lucknow and Dr. Vivek Bhosale, Scientist discussed on various aspects of Drug Design & Development, Pre-formulation Studies up to Scale-up, Pre-clinical safety evaluation of drug and Design & Review of Clinical trial protocol respectively.



Case studies were given to all the participants during the presentation by the faculties to make learning interactive and interesting and easy to understand the concept of the presentations.



Post- assessment of the participants on 24<sup>th</sup> January, 2014



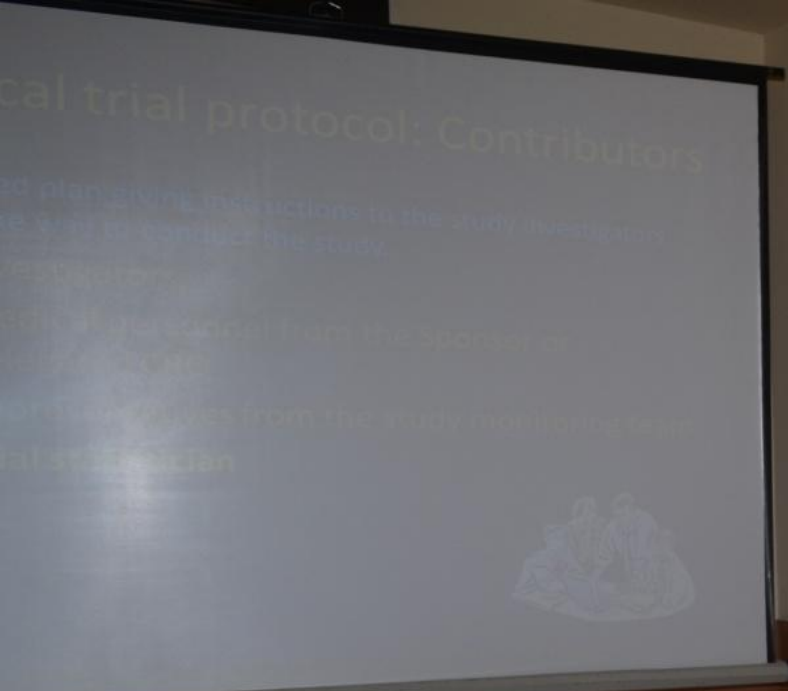
THE THIRD DAY I.E. 24<sup>TH</sup> JANUARY, 2014 WAS PLANNED FOR THE DRUGS INSPECTORS WHO REVIEW VACCINE CLINICAL TRIAL PROTOCOLS INCLUDING ADC (I) AND DDC (I) OF THE CONCERNED DIVISIONS. MR. S. P. SHANI, DEPUTY DRUGS CONTROLLER (INDIA) GAVE PRESENTATION ON VACCINE LICENSING AND PRE MARKET AUTHORIZATION.

# CHECK FOR.....

- ◆ Title-What phase of Vaccine Trial?
  - ◆ Why Vaccine trials?
  - ◆ ICH GCP – GMP Guidelines
  - ◆ Responsibilities of Investigator
  - ◆ Responsibilities of Sponsor
  - ◆ Phases of Vaccine Trial
- IEC IRB
  - Ethics in Vaccine Trials-Benefit vs risk
  - Informed Consent
  - Study Design
  - Adverse Events/ & Serious AE
  - Reporting
  - Compensation



DR. SANGEETA YADAV, PROFESSOR, MAULANA AZAD MEDICAL COLLEGE, NEW DELHI, DISCUSSED REVIEW OF CLINICAL TRIAL PROTOCOL AND REPORT OF VACCINES AND ALSO SHARED HER EXPERIENCE AS AN INVESTIGATOR OF CLINICAL TRIAL WITH THE CDSCO INSPECTION TEAM.



DR. M. KALAIVANI, SCIENTIST III, BIOSTATISTICIAN FROM AIIMS, NEW DELHI DISCUSSED CASE STUDY ON BIOSTATISTICS INVOLVED IN DESIGN OF CLINICAL TRIAL PROTOCOL AND REPORT OF VACCINE, ESTIMATION OF SAMPLE SIZE IN THE CLINICAL TRIAL AND ROLE OF BIOSTATISTICIAN FOR THE CALCULATION OF SAMPLE SIZE, STUDY DESIGN AND STATISTICAL ANALYSIS OF CLINICAL STUDY.



Rajaram Dharamraj  
Drugs Inspector, CDSCO (HQ)

Rajeshwar Mishra  
Drugs Inspector, CDSCO (HQ)

Drugs Inspector, CDSCO (HQ)

**GROUP DISCUSSION ON VACCINE CLINICAL TRIAL PROTOCOL**



**Participants for workshop**



**OUTCOME OF WORKSHOP:**  
**THE PRESENTATION, GROUP DISCUSSION AND CASE STUDIES DURING THE WORKSHOP COVERED ALL THE IMPORTANT FUNCTIONAL AREA INCLUDING SYSTEMATIC REVIEW OF CLINICAL TRIAL PROTOCOL OF BIOLOGICAL AND MEDICINAL PRODUCTS AND GAVE ALL THE PARTICIPANTS ADEQUATE KNOWLEDGE AND CAPACITY FOR EVALUATION OF DOCUMENTS. THIS WOULD BE USEFUL FOR THEM TO IMPLEMENT THE KNOWLEDGE WITH CAPACITY OF PROPER REVIEW AND ANALYSIS LEADING TO UNIFORM REGULATORY DECISIONS.**



**ORGANIZER OF THE WORKSHOP**