Workshop on "Review Procedure Adopted for Evaluation of New Drug Application, BA/ BE Study and Marketing Permission" from 24th – 27th February, 2014 at New Delhi

Objective of the Workshop

The primary objective of the workshop was to improve the understanding and reviewing capacity of BA/ BE data submitted as a part of new drug application and to train the Drugs Inspectors on inspections of BA/ BE study.

Agenda of the Workshop

24 February 2014 (Day 1):

S.No.	Topic	Time (Hr.)	Faculty/Facilitator
1	Registration	09:30 – 10:00	CDSCO
2	Theme / Key note address	10:00 – 10:30	CDSCO
3	Refreshments	10:30 – 10:50	--
4	Introduction to BA / BE study	10:50 – 11:20	Dr. Vishwas D Sangle Glenmark Generics Ltd.,
5	Study Specific Procedures & Clinical Pharmacology Unit	11:20 – 13:00	Dr. Gauri Patel Cliantha Research Limited
6	Lunch	13:00 – 13:45	--
7	Study related Documents	13:45 – 15:30	Dr. Munish Kaushik Jubilant Life Sciences Limited
8	Refreshments	15:30 – 15:50	--
9	Study Report	15:50 – 16:30	Dr. Munish Kaushik Jubilant Life Sciences Limited
10	Group Exercise & Case Studies	16:30 – 17:00	
11	Open House discussion	17:00 – 17:30	Participants

25 February 2014 (Day 2):

S.No.	Topic	Time (Hr.)	Faculty/Facilitator
1	Bio-analysis	09:30 – 10:30	Mr. Sandeep Sharma Jubilant Life Sciences Limited
2	Refreshments	10:30 – 10:50	--
3	Data Analysis Statistical Analysis	10:50 – 11:35	Mr.Rajneesh Singh Fortis Clinical Research Ltd
4	Group Exercise & Case Studies	11:35 – 12:30	--
5	Open House Discussion	12:30 – 13:00	--
6	Lunch	13:00 – 13:45	--

26 February 2014 (Day 1):

S.No.	Topic	Time (Hr.)	Faculty / Facilitator
1	Registration	09:30 – 10:00	CDSCO
2	Introduction	10:00 – 10:15	CDSCO
3	Pre Workshop Assessment	10:15 – 10:30	--
4	Tea / Coffee Break	10:30 – 10:50	--
5	Introduction to BA / BE study	10:50 – 11:20	Dr. Vishwas D Sangle Glenmark Generics Ltd.,
6	Study Specific Procedures & Clinical Pharmacology Unit	11:20 – 13:00	Dr. Gauri Patel Cliantha Research Limited
7	Lunch	13:00 – 13:45	--
8	Study related Documents	13:45 – 15:30	Dr. Munish Kaushik Jubilant Life Sciences Limited
9	Tea / Coffee Break	15:30 – 15:50	--
10	Study Report	15:50 – 16:30	Dr. Munish Kaushik Jubilant Life Sciences Limited
11	Group Exercise & Case Studies	16:30 – 17:00	
12	Open House discussion	17:00 – 17:30	Participants

27 February 2014 (Day 2):

S.No.	Topic	Time (Hr.)	Faculty / Facilitator
1	Bioanalysis	09:30 – 10:30	Mr. Sandeep Sharma Jubilant Life Sciences Limited
2	Tea / Coffee Break	10:30 – 10:50	--
3	Data Analysis Statistical Analysis	10:50 – 11:35	Mr.Rajneesh Singh Fortis Clinical Research Ltd
4	Group Exercise & Case Studies	11:35 – 12:30	--
5	Post Workshop Assessment	12:30 – 13:00	--
6	Lunch	13:00 – 13:45	--
7	Regulatory & Industrial Challenges in Bioanalytical & Monitoring Investigations of the Bioanalytical failures Phase I studies Vs BA/BE Studies	13:45 – 14:30	Dr. Rachna Arora Ranbaxy Laboratories Limited

List of Participants:

24th – 25th February:

S.No.	Facilitators	Designation	Organization
Resource Persons/Facilitators			
1	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO, HQ
2	Ms. Rubina Bose	Assistant Drugs Controller (India)	CDSCO, HQ
3	Dr. Vishwas D Sangle	Deputy General Manager	Glenmarks Generics Ltd.
4	Dr. Gauri Patel	-	Cliantha Research Ltd.
5	Dr. Munish Kumar Kaushik	Associate Director-PV	Jubilant Clincys Ltd.
6	Mr. Sandeep Sharma	Director-BA/BE	Jubilant Life science Ltd.
7	Mr. Rajneesh Singh	Senior Biostatistician	Fortis Clinical Research Ltd.
Participants			
8	Mr. Amol Eknath Kandekar	Drugs Inspector	CDSCO, HQ
9	Mr. Manish Singhal	Drugs Inspector	CDSCO, HQ
10	Mr. P. Manavalan	Drugs Inspector	CDSCO, Chandigarh
11	Mr. Deshraj Singh	Drugs Inspector	CDSCO, WZ
12	Ms. Sarala Devi	Drugs Inspector	CDSCO, Hyderabad
13	Mr. Deepak Kumar	Drugs Inspector	CDSCO, WZ
14	Mr. Suresh Kumar Kalwaniya	Drugs Inspector	CDSCO, HQ
15	Ms. Nisha Kaushik	Drugs Inspector	CDSCO, HQ

16	Mr. Saurabh Garg	Drugs Inspector	CDSCO, HQ
17	Ms. Sudarmathi S	Drugs Inspector	CDSCO, HQ
18	Mr. Popat Dattatraya Thorat	Drugs Inspector	CDSCO, HQ
19	Dr. Kasi Sankar	Drugs Inspector	CDSCO, HQ
20	Mr. Devendra Nath	Drugs Inspector	CDSCO, HQ
21	Mr. Rahul Panwar	Drugs Inspector	CDSCO, HQ
22	Ms. Sunitha Seerapu	Drugs Inspector	CDSCO, HQ
23	Mr. Bidya Sekhar Mishra	Drugs Inspector	CDSCO, HQ
24	Mr. V Sooraj	Drugs Inspector	CDSCO, HQ
25	Mr. Basant Kumar Yadav	Drugs Inspector	CDSCO, HQ
26	Dr. Vijai Singh Karwasara	Drugs Inspector	CDSCO, HQ
27	Mr. Pushpraj Kumar Singh	Drugs Inspector	CDSCO, HQ
28	Mr. Avinash Kumar Yadav	Drugs Inspector	CDSCO, HQ
29	Mr. Dileep Kumar	Drugs Inspector	CDSCO, HQ
30	Mr. Shabeer Ashfaque Abdulla	Drugs Inspector	CDSCO, HQ
31	Mr. Rahul Singh	Drugs Inspector	CDSCO, HQ
32	Mr. Pratyush Kumar	Drugs Inspector	CDSCO, HQ
33	Mr. Bikramaditya Chowdhury	Drugs Inspector	CDSCO, HQ
34	Mr. Bibekananda Behera	Drugs Inspector	CDSCO, HQ
35	Mr. Jay Jyoti Roy	Drugs Inspector	CDSCO, HQ
36	Ms. Kiran Singh	Drugs Inspector	CDSCO, HQ
37	Dr. Bikash Roy	Drugs Inspector	CDSCO, HQ
38	Mr. Navneet Pratap Singh	Drugs Inspector	CDSCO, Goa
39	Mr. Ashok	GM	Cliantha Research Ltd.40
40	Dr. Ashwini Sawant	Research officer	Glenmarks Generics Ltd41
41	Mr. Anshuman Rai	Executive	Glenmarks Generics Ltd.
42	Mr. Kuldeep Namdev	Pharmacokinetic Scientist	Fortis Clinical Research Ltd.

26th – 27th February:

S.No.	Facilitators	Designation	CDSCO Office
Resource Persons/Facilitators			
1	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO, HQ
2	Ms. Rubina Bose	Assistant Drugs Controller (India)	CDSCO, HQ
3	Dr. Vishwas D Sangle	Deputy General Manager	Glenmarks Generics Ltd.
4	Dr. Gauri Patel	-	Cliantha Research Ltd.
5	Dr. Munish Kumar Kaushik	Associate Director-PV	Jubilant Clincys Ltd.
6	Mr. Sandeep Sharma	Director-BA/BE	Jubilant Life science Ltd.
7	Mr. Rajneesh Singh	Senior Biostatistician	Fortis Clinical Research Ltd.
Participants			
8	Mr. Saurabh Garg	Drugs Inspector	CDSCO, HQ
9	Mr. Devendra Nath	Drugs Inspector	CDSCO, HQ
10	Mr. Ashok Kumar	Drugs Inspector	CDSCO, WZ
11	Ms. Nisha Sankhwar	Drugs Inspector	CDSCO, HQ
12	Mr. Ashok Kumar Yadav	Drugs Inspector	CDSCO, Ahmedabad
13	Mr. Virendra Singh	Drugs Inspector	CDSCO, Ahmedabad
14	Mr. Rajaram Dharamraj	Drugs Inspector	CDSCO, HQ
15	Mr. Dharmvir Singh	Drugs Inspector	CDSCO, HQ
16	Mr. C. Arunachalam	Drugs Inspector	CDSCO, HQ
17	Mr. Ankur Bansal	Drugs Inspector	CDSCO, HQ
18	Mr. Dinesh Kumar	Drugs Inspector	CDSCO, HQ
19	Mr. Sourabh Mittal	Drugs Inspector	CDSCO, HQ
20	Mr. Sunil Kumar Malviya	Drugs Inspector	CDSCO, HQ
21	Mr. Abhinav Kapoor	Drugs Inspector	CDSCO, HQ
22	Mr. Deepak Kumar Sehrawat	Drugs Inspector	CDSCO, HQ
23	Mr. Akash Rama Kondalkar	Drugs Inspector	CDSCO, HQ
24	Ms. A Anbuselvi	Drugs Inspector	CDSCO, HQ
25	Mr. J.Sureshkumar	Drugs Inspector	CDSCO, HQ

26	Mr. Saurabh Jain	Drugs Inspector	CDSCO, HQ
27	Ms. C. Thiruvidha	Drugs Inspector	CDSCO, HQ
28	Mr. Rakesh Negi	Drugs Inspector	CDSCO, HQ
29	Mr. Parthiban J	Drugs Inspector	CDSCO, HQ
30	Mr. Arvind Singh Panwar	Drugs Inspector	CDSCO, HQ
31	Mr. Surender Kumar Kaswan	Drugs Inspector	CDSCO, HQ
32	Mr. Haribabu J	Drugs Inspector	CDSCO, HQ
33	Mr. Baljeet Sihag	Drugs Inspector	CDSCO, HQ
34	Ms. Suniti Choudhary	Drugs Inspector	CDSCO, HQ
35	Mr. Sachin Yadaorao Bhagwate	Drugs Inspector	CDSCO, HQ
36	Mr. Sri Babu	Drugs Inspector	CDSCO, HQ
37	Mr. Sandeep Kumar	Drugs Inspector	CDSCO, HQ
38	Mr. Manoj Choudhary Jatav	Drugs Inspector	CDSCO, HQ
39	Mr. Fahim Khan	Drugs Inspector	CDSCO, HQ
40	Mr. Mohan R.	Drugs Inspector	CDSCO, HQ
41	Mr. Manish Horo	Drugs Inspector	CDSCO, HQ
42	Mr. Balakumar Mahalingam	Drugs Inspector	CDSCO, HQ
43	Mr. Arun Kumar Prashar	Drugs Inspector	CDSCO, HQ
44	Mr. S. Gopinath	Drugs Inspector	CDSCO, NZ
45	Mr. Kailash Malik	Drugs Inspector	CDSCO, EZ
46	Mr. Anshuman Rai	Executive	Glenmarks Generics Ltd.
47	Mr. Kuldeep Namdev	Pharmacokinetic Scientist	Fortis Clinical Research Ltd.

Two days workshop on “Review procedure adopted for Evaluation of New Drug Application, BA/ BE Study and Marketing Permission” was carried out in two batches i.e. Batch-1 and Batch-2 from 24th – 25th February 2014 and 26th – 27th February 2014 respectively.

Of the two days workshop, there were presentations by different representatives from the various BA/BE centers on both the days and there was a meeting between Stakeholders and CDSCO Officials on 25/02/2014 during post lunch session regarding various issues related to the BA/BE study in India.

There were presentations by different representatives from the BA/BE study centers. They discussed about need of BA / BE study, types of study, various components of BA/BE study protocol, study design, parameters to be evaluated, dose regimen, inclusion & exclusion criteria, statistical methods planned in the protocol and determination of sample size, efficacy evaluation, statistical analysis, introduction of ANDA & generics, practical approach to bioequivalence studies, regulatory requirement for BA/BE study reliable range of quantification, ULOQ, LLOQ, dilution, how well can the drug be measured in this range, Accuracy, precision, selectivity, how does sample handling affect the reliability of the measurement, Freeze-thaw, room temperature handling, injector stability, short, long term-stability, statistical analysis of data etc.

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 addressing the participants about the importance of the workshop.

Presentations by different Speakers during Workshop






Participants during workshop (Batch-1)






Participants during workshop (Batch-2)






Participants during Pre-assessment and Post-assessment (Batch-1)

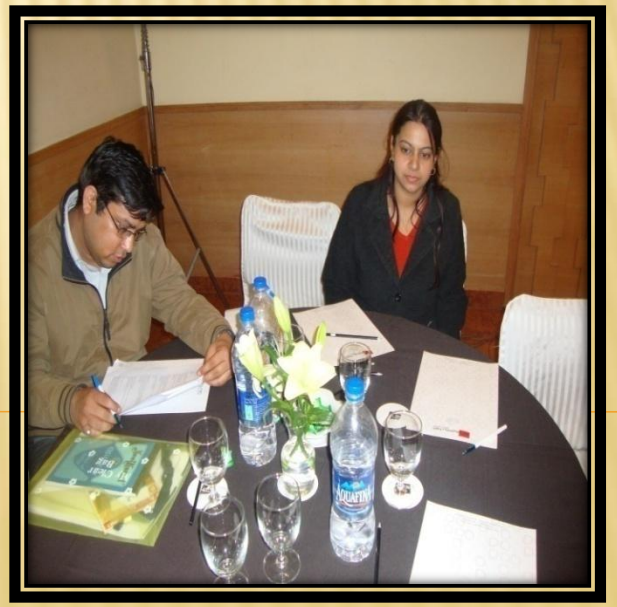





Participants during Pre-assessment and Post-assessment (Batch-2)





Participants during Pre-assessment and Post-assessment (Batch-2)

Dr. G.N. Singh, Drugs Controller General (India) addressing the Stakeholders on 25 February 2014

Dr. V.G. Somani,
Joint Drugs Controller (India)
addressing the Stakeholders

Dr. A. Ramkishan,
Deputy Drugs Controller (India)
addressing the Stakeholders




Discussion of DCG(I) staff and various Stakeholders

Group Photograph during the Closing Ceremony of Workshop (Batch-1)

Group Photograph during the Closing Ceremony of Workshop (Batch-2)

OUTCOME:

- Introduction to BA/BE studies such as definition, type, design of BA/BE study etc.
- BA/BE study protocol and its crucial components.
- Regulatory requirements of BA/BE studies.
- Role of statistical tool in evaluation of BA/BE data.
- Basic knowledge of Bioanalytical methods and method development.
- Knowledge of clinical sample analysis.
- Interpretation of the Clinical & Pharmacokinetics data, Statistical data and study protocol.
- Awareness on general requirement for the dossier submission to NRA.
- Knowledge on Guidance for Industry Requirements for permission of BA/BE Approval.