VEEDA CRO deliberated a talk on Study Design Considerations of Bioequivalence Studies in the workshop organized by CDSCO – New Delhi

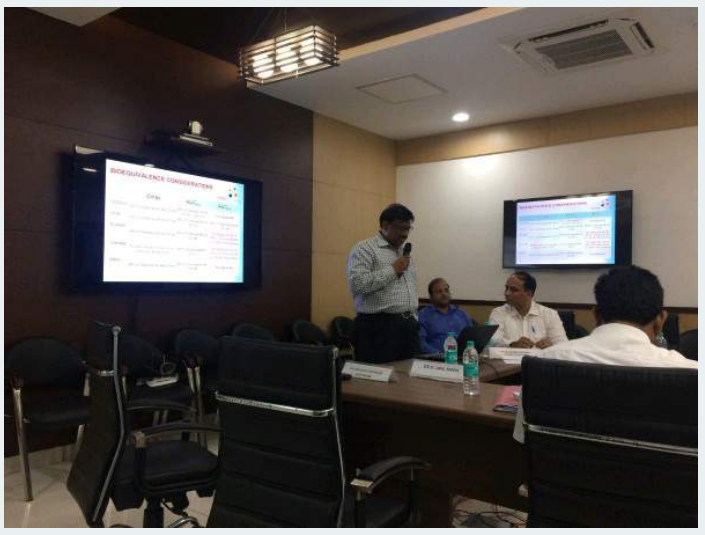
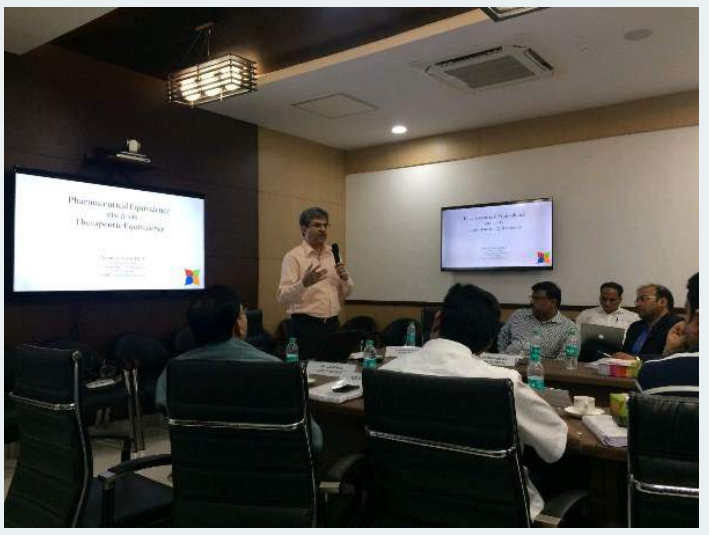
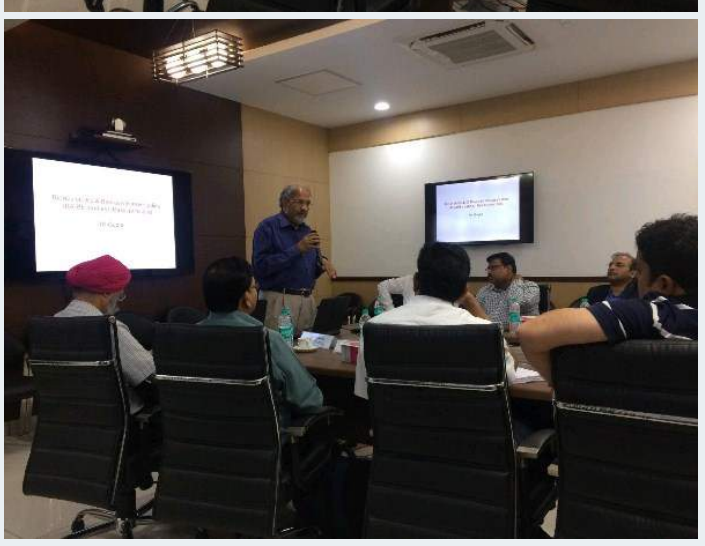
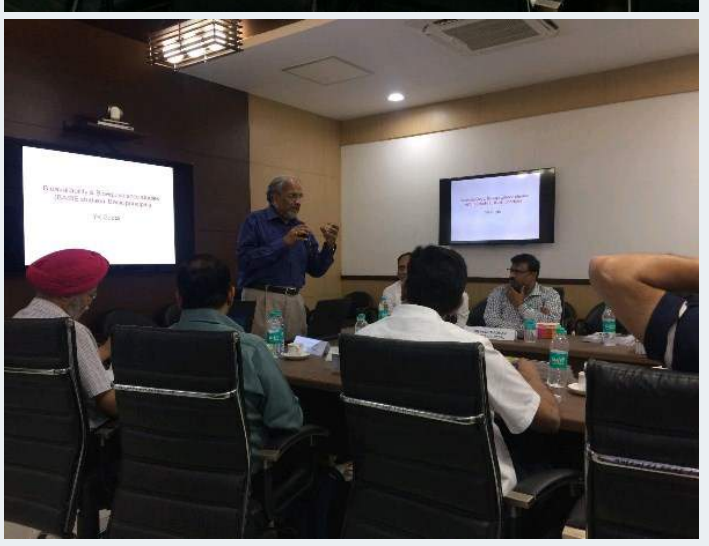
On 2nd June 2018, New Delhi , A workshop was organized by CDSCO office - New Delhi for all state drug controllers to deliberate issues regarding the implementation of bioavailability and bioequivalence studies of Pharmaceutical formulations.

As per recently amended DCC rules, 1945 applicants shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs under the category II and IV of the Biopharmaceutical Classification System.

In the workshop Honorable DCGI Dr. Eswar Reddy discussed the objectives of CDSCO office in implementing newly amended DCC rules and also shared his vision on the way forward pertaining to the implementation of the same.

Dr. Venu Madhav, COO of Veeda Clinical Research Organization delivered a talk on 'Study Design considerations of Bioequivalence Studies' in this workshop. He discussed about relevance of generics drugs and bioequivalence studies, different types of bioequivalence studies and various aspects of bioequivalence study design considerations with practical examples in line with CDSCO, USFDA, EMA, WHO etc regulatory requirements. This workshop was quite interactive and appreciated by all. This workshop helped to have a common platform to deliberate and learn from each other about the implementation of recently amended DCC rules.

The talks of subject matter experts from LHMC – New Delhi, Department of Pharmacology, AIIMS, NIPER, ZYDUS CADILA and CDSCO on topics like Pharmacodynamics & Pharmacokinetics, Bioavailability & Bioequivalence studies of Drugs, Pharmaceutical equivalence ,Assessment of BE study protocol and report, Validation of Bio analytical methods, Pharmacokinetic analysis and criteria of bioequivalence, Regulatory framework for BE study and different method for establishing Bioequivalence made this work shop a memorable good learning experience for every one present.

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