

2. “Changing Scenario in the Drug Regulatory Affairs 2008”

The AICTE sponsored national seminar “*Changing Scenario in the Drug Regulatory Affairs*” was conducted on 8th -10th March, 2008 by PDM College of Pharmacy. These three days conference was essentially focused on different aspects of Drug Regulatory Affairs. This Seminar symbolized the crystallization of the will of authorities towards achieving a comprehensive approach to regulate and enrich us with the changes in the drug regulatory requirements. Veterans from the field of DRA from teaching fraternity as well as industries gave their valuable contributions on various regulatory aspects.

As it is rightly said that all good things start with prayers so was the Inaugural function which started with Saraswati Vandana, followed by lightening of lamps.



The welcome note was given by Dr. Arun Garg to all the guests & delegates. The occasion was graced by Joint Secretary, PDMREA, Mr. R.P.Rawat. On the fist of the seminar Dr. Sushma Gupta, Associate Director, Ranbaxy Research Laboratories, Gurgaon who was the chief guest enlightened delegates on the topic “*Industry Academia Interaction Industry’s Prespective*”. Next presentation was given by the guest of honors Dr. P.C. Deshmukh, Head of Regulatory Affairs, IPCA Labs. She enhanced the quality and potency of this seminar by revealing her expertise knowledge on the topic “*The Brave New World of Pharma*” The third presentation was given by Mr. Atul Nasa (Drug Control Deptt.) who briefed on the topic “*Types of Inspection*”

The scientific session started in the afternoon & was headed by Dr. Bharti Khanna (Director, Regulatory Affairs, Ranbaxy Research Laboratories, Gurgaon. Her topic of discussion was “*The Hub in the Pharmaceutical industry wheel*” and she discussed why rules & regulations are necessary the regulatory scenario & role of regulatory affairs. She also gave details regarding the common technical document format. Next speaker of the scientific session was Mr. P.P. Sharma (Ex. Drug Controller) & he gave a stimulating talk on “*Quality Assurance Basic Concepts*”.



On 9th March, 2008 (2nd day of the scientific session) was commemorated by Dr. R.A. Singh, Director Technical, Arbro Pharmaceutical Ltd. He briefed us on “History of Principal Pharmacopoeia 2007”. He said that I.P. 2007 is the yardstick of quality & it maintains all International standards. It contributes in the control of quality of medicinal products. Next speaker was Ms. Jaspreet Kochar, who is a seasoned personality in the field of DRA. She shared her expertise on the topic “FDA process for approving generic drugs. The session was concluded by Dr. Arun Nanda, HOD of Pharmaceutical Sciences, MDU, Rohtak. He is an eminent personality in Pharmaceutical fraternity. He enlightened us on the topic “Regulatory Consideration for Biosimilars”. The afternoon session was taken over by Mr. Ravi Dahiya (Officer, Corporate Quality Assurance, IPCA Labs, Mumbai) on the topic “Regulatory Aspects of Medical Devices in India”. The session was concluded by Ms. Kirti Yadav from Kinapse on the topic “Global Harmonization Initiatives & India”. The scientific session of the third & the last day consisted of some of the eminent personalities from Pharma Academia and Industry.



The session initiated with a talk from Dr. S.S. Aggarwal, Principal, DIPSAR, who was also the esteemed chief guest for the valedictory function of the seminar. The topic of his talk was “Need for Regulations of Cosmetics, Manufacture & Sale & Pharmacovigilance of Cosmetics” He laid strong emphasis that there is an urgent need to implement regulations on various cosmetics which are used in day to day life. Next speaker was Dr. Vijay Bhalla, Principal, College of Pharmacy, IIGM, Greater Noida. The topic of his talk was “Medication Safety”. The next speaker was Mr. S.L. Nasa who is a renowned figure in field of Pharmacy. He delivered his talk on “Challenges & Opportunities for Pharmaceuticals in Health Care in India.” Mr. Shailender Kumar Singh, Reader, Pharmaceutics department was also one of the speakers of the last day. He enlightened the delegates on the current scenario of “Pharmacodynamic & Pharmacokinetic Drug Interaction”.