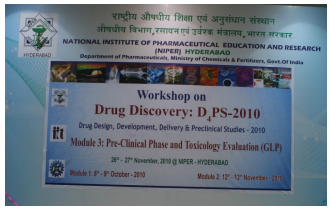

A workshop entitled 'Drug Discovery: Drug Design, Development, Delivery and Pre-clinical Studies (D_4PS-2010)' had been jointly organized by National Institute of Pharmaceutical Education and Research (NIPER) Hyderabad and Indian Institute of Chemical Technology (IICT), Hyderabad. It is designed in a series of three modules, each one with duration of two days. Module-1 was on Drug Discovery and Development Overview (8th & 9th October, 2010), Module-2 was about Dosage Form Development & Novel Drug Delivery Systems (12th & 13th November, 2010), and Module-3 scheduled on 26th & 27th November, 2010 and it is about Pre-clinical Phase & Toxicology Evaluation.

About NIPER-Hyderabad: National Institute of Pharmaceutical Education and Research (NIPER) is an autonomous body and established under the aegis of Department of pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt. of India, at Hyderabad as a centre of excellence for higher education, research and development in pharmaceutical sciences. The institute has been declared as an "Institute of National Importance" by Government of India through an Act of Parliament (NIPER ACT 1998 & NIPER Amendment ACT 2007). It is offering Post Graduate Programmes in Pharmaceutical Sciences.

About IICT: Indian Institute of Chemical Technology (IICT), Hyderabad is a premier Council of Scientific and Industrial Research (CSIR) R&D Institute in India. Major areas of research at IICT are: Pharmacology, Natural Products Chemistry, Drugs & Intermediates, Chemical Engineering, Lipid Sciences & Technology, Agrochemicals, Fine Chemicals, Fluoro-Organics, Inorganic & Physical Chemistry (Catalysis & Materials Science), Coal, Gas & Energy. With highly professional scientists, an excellent laboratory and instrument facility for research, IICT is known internationally for its contribution to both basic and applied sciences.

There are large number of private and government educational institutes in and around Hyderabad offering graduate and post-graduate courses in Science and Pharmacy. The students coming from some of these establishments are not adequately trained in modern topics necessary for Pharmaceutical Industry to take-up challenging assignments in Drug Discovery. Hence, services of training in teaching and practical skills in modern areas of drug development are in large demand by the pharmaceutical industries for the future development in India. This workshop is aimed to impart training and discuss the current advances in Drug Discovery and Development. The target audience is from Industry, Academia and Students. Workshop methodology includes lectures, panel discussions, demonstrations, case studies and hands-on exercises for the participants with eminent speakers.

The Module III workshop on Drug Discovery: D4PS was inaugurated by Dr. Ahmed Kamal, Project Director, NIPER-Hyderabad. Dr. Kamal in his welcome address mentioned the importance of these short term workshops. He emphasized that the NIPERs objective is to train the students in specialized areas and to face the future needs of the Pharmaceutical industry. Dr. Kamal also mentioned that the Ministry of Chemicals and Fertilizers, Govt. of India are encouraging such short term workshops. He thanked Novartis, Hyderabad for active participation in conducting the workshop. Dr. Vivek Devaraj, Head of Global Pharma Operations, Novartis elaborated on the important aspects in fulfilling the strategies and needs in the Drug Discovery & Development. He said that this can be achieved by means of rapid global access and by building a dynamic learning activity. Dr Amit Khanna, Novartis, Hyderabad gave a brief review on Module-III. In the inaugural session, Prof. N. Satyanarayana, Registrar; Dr. S. Ramakrishna Course Coordinator; Dr. A. Krishnam Raju, Convener; Faculty of NIPER-Hyderabad; Dr. V. Jayathirha Rao, Scientist, IICT, invited speakers and delegates were present.

Dr. J. B. Gupta, GVK Bioscience, Hyderabad, in his talk on Drug Discovery and Development explained the various problems faced by the pharma companies in the innovation of a new molecule. He concluded that there was a need for using knowledge in genomics, proteomics, transgenic animal models, imaging technologies, structural biology and biochemistry in developing new tools that can be applied in the lab. Dr. Swaroop kumar, Incozen Therapeutics gave a fascinating and educative talk on Biopharmaceutical issues in Preclinical Drug Development. The key role of biopharmaceutics and its critical properties to be considered in preclinical drug development were discussed.

Dr. Shashivardhan, Scientist, IICT, delivered a lecture on Target identification and validation. In his talk he explained methods for target identification, limitations on CNS research, biochemical manifestations in PD, mechanism mediating alpha-synuclein functions. Dr. Anthony, Scientist, IICT has continued the topic of target identification and validation. He explained in depth on angiogenesis, tumor growth inhibition with TNP-470, target identification, classification of Met APS, crystal structure of Met AP1 in complex.

Dr. Giridaran, NIN, Hyderabad had delivered an interesting lecture on the use of animals in biomedical research, major areas of lab animals used and care to be taken into consideration for conducting the study. He explained the guidelines to be followed and various other aspects to be considered. He concluded the topic with the public policies to be adopted while performing the studies.

The post-lunch session was started by Dr. Rajesh Karan, Novartis. He focused on Drug discovery approaches, sources of new molecular entities, phases in pre-clinical drug development, screening to hit to lead paradigm and profiles of a lead compound. He also mentioned the importance of *in vitro* biochemical assay methods and detection techniques used in screening of molecules. Dr. Vyas M Shingatgeri, Ranbaxy Research labs., Gurgaon, described the significance of safety pharmacology in drug discovery and drug development. He mentioned reasons for development failure, historical perspectives, major causes of acute drug reactions and main reasons for drug discontinuations. He concluded his talk with the role of pharmacology studies, safety pharmacology and its objectives, and how pharmacology plays a significant role in study design and in dose fixation in phase I clinical trials.

Dr. Subramanian, Novartis, delivered an interesting lecture on *In vitro* methods of DMPK. He explained the background in the in vitro methods in early development, role of DMPK in lead optimization, metabolite stability, electron flow in microsomal drug oxidising system. The contribution of enzyme in drug metabolism permeability cell lines, CaCo-2 permeability and about plasma binding and regulatory perspectives were described in detail. On first day of workshop case studies were conducted by him on calculations on FIH dose. After the presentations of various teams, the day session ended with the cultural programmes performed by the NIPER-Hyderabad students.

The first talk of second day was started by Dr. Dinesh Kumar, Scientist, NIN Hyderabad. He delivered a fascinating lecture on the toxicology testing, methodology and regulatory perspectives. The importance of preclinical and its data, in new drug phases of drug discovery and how to proceed for a clinical trial were emphasized by him.

Dr. Ashwini Mathur, Head, Novartis explained how to apply the statistics in pre-clinical studies. He covered the fundamental considerations in assessing the need of guidelines in carcinogenicity studies. He concluded that the drugs should be tested for CNS, CVS and RS before giving to the humans. Prof. V. Laxmipathi, Kakatiya University (Retd. Prof.) delivered a lecture on special toxicology studies, genotoxicity and their applications. The general overview of the science of mutagenicity and carcinogenicity and cellular mechanism of homeostasis were explained. The AMES test for recognition of mutagen, transgenic models, and silico model were also discussed. Dr. Venugopal Peta, Novartis has delivered a lecture on general principles of GLP Toxicology and their applications. He explained in detail about the evolution of Good Laboratory Practice, Organisation for economic Co-operation and development (OECD), principles of GLP and their application in research.

In the afternoon session, Dr. Geeta Rajashekar – Qualtox Consultancy, gave a lecture on Principles of Good Laboratory Practice-OECD perspective. Dr. Rajashekar emphasized the basic requirements for compliance to the OECD principles of GLP and discussed the extension of these principles into other areas of non-regulatory research work, animal facilities, SOPs, characterisation of test and reference items. For the workshop, all the delegates were divided into 10 equal groups and were given case studies. The participants were asked to study them, discuss among their team mates and present the information required. Dr. Geeta Rajashekar gave case studies on Standard Operating Procedures (SOP) to the participants for discussion and presentation.

The workshop was organized by Prof. J. S. Yadav, Director, IICT; Dr. Ahmed Kamal, Project Director; Prof. N. Satyanarayana, Registrar; Dr. R. Srinivas, Dr. S. Ramakrishna, Prof. V. Peesapati; Prof. Nalini Sastry, Dr. Kolupula Srinivas, Dr. Bathini Nagendra Babu, Dr. A. Krishnam Raju (Convener), Dr. N. Shankaraiah, Dr. Narendra Kumar Talluri, Dr. S. Gananadhamu, Dr. T. Venu, Dr. S. Sunitha, Dr. Satish, Dr. Vidya Sagar, Dr. Arifuddin from NIPER-Hyderabad. This workshop was supported by Novartis under the knowledge sharing initiative. The supporting staff of NIPER-Hyderabad and IICT also actively contributed in the workshop. The workshop was attended by delegates from IICT, NIPER, various pharmacy colleges and industries all over India. The delegates and speakers of the workshop have appreciated the way the workshop was organized and conducted by NIPER-Hyderabad. They also expressed that NIPER should conduct such useful workshops in future.

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