



National Institute of Pharmaceutical Education and Research (NIPER) Hyderabad and Indian Institute of Chemical Technology (IICT) have jointly

organized a workshop entitled 'Drug Discovery: Drug Design, Development, Delivery and Preclinical Studies (D<sub>4</sub>PS)'. 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, scheduled on 8<sup>th</sup> & 9<sup>th</sup> October, 2010, Module-2 was about Dosage form Development and NDDS (Emerging Technologies), scheduled on 12<sup>th</sup> & 13<sup>th</sup> November, 2010 and Module-3 is about Preclinical Phase and Toxicology Evaluation (GLP), scheduled on 26<sup>th</sup> & 27<sup>th</sup> November, 2010.

About NIPER-Hyderabad: National Institute of Pharmaceutical Education and Research (NIPER) is an autonomous body and established under the aegis of Ministry of Chemicals & Fertilizers 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.



current advances in Drug Discovery and Development. The target audience are from Industry, Academia and Students. The workshop methodology includes lectures, panel discussions, demonstrations and hands-on exercises for the participants with eminent scientists from the Academia & Industry.



The Module II workshop on Drug Discovery: D<sub>4</sub>PS was inaugurated by Prof. N. Satyanarayana, Registrar, NIPER-Hyderabad and Dr. Amit Khanna, Group Head, Global Regulatory CMC at Novartis, Hyderabad. Dr. Ahmed Kamal, Project Director, NIPER-Hyderabad in his welcome address, mentioned that this workshop is unique in nature as it has three modules spanned over a period of two months time. He commented on the positive feedback given by the participants from Module I. He also highlighted the various activities and recent developments of NIPER-Hyderabad. In the inaugural session, Dr. R. Srinivas and Dr S. Ramakrishna Course Coordinators, Faculty of NIPER-Hyderabad were present.

Dr. Amit Khanna, Novartis, Hyderabad, in his talk on New Product generation gave an overview of Drug development stages and need for NDDS. He discussed different types of NDDS currently available in the market and highlighted the need for such complex technologies citing few case studies. He concluded that NDDS not only improves the patient compliance but also helps in increasing market potential. Dr. J Ashok Raj, DRL discussed various aspects of IVIVC. He enlightened the participants on different terminologies involved in IVIVC, various levels of IVIVC and the methods involved in obtaining successful IVIVC which he elaborated by citing various case studies reported in literature in the later part of his presentation.



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 pharmaceutical and higher educational institutions. 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



Dr. Rambhau, Advisor, NDDS Division, NATCO Research Centre, Hyderabad, delivered a lecture on Functionalized liposomal Nano-Carriers for Drug Delivery. He described the concept of magic bullet, origin, types and classification of nano-technology. The application of liposomal nano-carriers in targeting the brain using BBB transporters or targeting to an inflammatory site using

specific nano-technology was described in detail based on various *in vivo* data presented by him. Dr. S. S. Apte, VP, NDDS Division, NATCO Research Centre, Hyderabad described the fundamentals behind formulation of liposomes, the mathematical concept involved in formulating a successful liposomal DDS, the various manufacturing techniques involved in preparation and sizing of liposomes and their characterization methods. He discussed the importance of various quality control parameters that could be used to identify the performance and shelf life of a formulated liposomal DDS.



The first talk of second day was given jointly by Dr. Jagannath Kota, a Senior Scientist at Novartis Hyderabad and Mr. Parag Borde, Novartis, Hyderabad. The talk covered various applications of Modified Release dosage forms, development of MR products and need for designing of MR prototypes at each stage of drug development. Various novel concepts such as Enterion and Intellcaps were also discussed. Prof. Y. Madhusudan

Rao, Kakatiya University, delivered a lecture on the emerging area of self regulated systems and pulsatile systems. The feedback mechanism involved and the immense potential over traditional DDS were highlighted. The concept of chrono-pharmaceutics and various programmable DDS using pH independent systems, time dependent or micro-flora activated systems were discussed in detail citing various case studies.



Dr. Ajay K Singh, DRDO gave an fascinating and an educative talk on Nuclear medicine imaging. The importance and application of this imaging technique and gamma-scintigraphy as a non invasive technique for evaluation of NDDS was discussed. Dr. Nalini Shastri, NIPER Hyderabad, discussed the role of NDDS in pediatric and geriatric patients with special emphasis on Fast disintegrating DDS. The various types of FDDS commercially available, manufacturing techniques and the patented technologies involved to obtain desirable product attributes were reviewed.



The Module II comprised of two workshop in the afternoon session on both days. These workshops were designed to give hands on experience on a few areas related to Drug development. 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. On first day, workshop was conducted on Submission Documents for NDDS. Dr Ranjani Nellore, Pharmantra and Dr. Amit Khanna, Novartis, Hyderabad conducted this session. Dr. Ranjani Nellore introduced the delegates to the definitions and terminologies involved in CTD. She also highlighted the

importance of CTD and gave a brief overview of various documents that were usually submitted for registration under CTD. On the second day of Module II, Dr. Jagannath Kota, and Mr. Parag Borde, gave case studies on IVIVC to the participants for discussion and presentation. In his introductory talk he gave a brief overview of IVIVC and methodology involved.



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 from NIPER-Hyderabad. This workshop is supported by Novartis under the knowledge sharing initiative. The supporting staff of NIPER-Hyderabad and IICT also actively contributed in the workshop. The response from institutes and industry was overwhelming in spite of a short notice about the workshop.

The workshop was attended by delegates from IICT, NIPER, various pharmacy colleges and industries all over India. The participants expressed that the lectures and workshops in Module-II relevant to current developments taking place in the area of formulations development in Pharmaceutical Industries.



Note: Schedule of **Module-3 (26-27<sup>th</sup> Nov' 2010)**

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