HYDERABAD

News Letter

DRUG DEVELOPMENT: CONCEPTUALISATION TO COMMERCIALISATION (D_2@C_2)

Module-I

A workshop on "Drug Development: Conceptualisation to Commercialisation" (D_2 @ C_2) was organized by NIPER-Hyderabad with the support of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India and Initiative support for knowledge sharing by Novartis, Hyderabad during 30th August – 1st Sep 2012 at NIPER– Hyderabad campus.

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 proclaimed to be 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). This institute offers M.S (Pharm) & Ph.D programmes in 4 disciplines *viz*., Medicinal Chemistry, Pharmaceutical Analysis, Pharmacology & Toxicology and Pharmaceutics. MBA (Pharma) has been commenced from the academic year 2012. NIPER-Hyderabad is mentored by Indian Institute of Chemical Technology, Hyderabad.

About D_2@C_2 Workshop: The workshop has invited lectures by eminent scientists/professors from industry/academia in the field of drug discovery, development and commercialization. Lecture sessions are accompanied by hands-on drug discovery experience and demonstration of special techniques in relevant topics. The main goal of the workshop is to build and enhance knowledge and skills of students and professionals working or intending to work in drug discovery, development and commercialization awareness. It is designed as three modules and whole workshop is divided into three modules, each module of three days duration, over a period of three months:

Module 1: Drug Discovery, Pre-clinical and Clinical (30th, 31st August- 1st Sep, 2012)
Module 2: Medical Writing, Regulatory Affairs & Pharmacovigilance (27th - 29th Sep, 2012)
Module 3: Product Development, Analytical, IPR & Marketing (18th – 20th Oct, 2012)

Module 1 (Drug Discovery, Pre-Clinical and Clinical): This module focused on the different phases from which a drug has to pass from its identification to clinical trials. Pre-Clinical and Clinical trials are gaining importance in today's scenario because of more stringent ethical conduct and guidelines. Hence it becomes even more essential to acquire the understanding of these phases in drug discovery which can help to make the path of drug development easy by eradicating problematic steps.

Registrations: Delegates consist of eminent scientists and faculty of life sciences and pharmaceutical sciences from academics & industry, research scholars and master students of life sciences and pharmaceutical sciences from all over India also participated the Workshop.

Dr. Ahmed Kamal, Project Director welcomed the gathering and in his inaugural address, highlighted the objective of the workshop and mentioned the recent developments in Pharmaceutical Sciences and highlighted its role in current scenario. He briefly naratted the role of IICT, Mentor institute of NIPER- Hyderabad in drug development. Dr. Kamal hoped that by 2020, Hyderabad will become the drug discovery hub. Dr. Kamal thanked Novartis for its help to organize current event.

From Novartis side Dr. Madhu Pudipeddi focused on the importance of such workshops and conferences and these workshops help the students to update themselves in the field of the drug development. He emphasized the need of talent in multidisciplinary pharmaceutical field. He said that the talent is the core competency interest in global function and fuel for pharmaceutical industries. With the help of presentation he later explained the growth of Novartis in Hyderabad.

Dr. Ramesh Bhambal, Daiichi Sankyo India Pharma Pvt. Ltd, Gurgaon has delivered a talk on "ADME screening Strategies for lead Optimization". In his talk, he elaborated the use of ADME animal models for screening large number of molecules for therapeutic effects.Dr. Dinesh Kumar, Scientist E, National Institute of Nutrition(NIN), Hyderabad has delivered a talk on "Current Drug Discovery Paradigm in Preclinical Process". He began his talk by explaining the term called, "Drug Epidemiology" and spoke about the importance of understanding the basics of drug usage to the safety issues associated with these drugs. He pointed out the regulatory and safety issue related to upcoming drug delivery systems like Nanoparticles, Stem cell, Neutraceuticals etc. He said that there is a paradigm shift in drug development from clinical pharmacology to reverse pharmacology from newer drug delivery systems. Dr Julius Anthony Vaz, Global Program Medical Director, Novartis has spoke on "Global Clinical Development". In his talk he discussed about how the whole process taking place in the clinical industries. He explained that the clinical trials are an ethical experiment aimed at answering precisely framed questions, by taking many examples like Insulin, Cerebral hemorrhage drugs etc.

The first day of afternoon session was designed to give hands on experience on a GLP by Dr Geeta Rajashekhar, Qualtox Consultancy, Bangalore. All the delegates were divided into 12 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 the second day, Dr. Ashiwini Mathur, Novartis precede with opening remarks about 2nd day activities and later invited Dr. B Unnikrishnan, Prof & Head of community Medicine, Kasturba Medical College, Manglore, Manipal, who gave an interesting lecture on "Designing and Conducting a Good Quality Clinical Trials". He spoke about good quality in clinical trials. He also explained different biases in clinical trials and discussed ways to eliminate those biases.

Dr. Mahesh Iyer, Novartis explained the participants about designing clinical trials protocol and gave 2nd day workshop task to the participants. After the tea brake the session was taken over by Dr. P. Usharani, NIMS, Hyderabad. She took a topic related to "Ethical issue related with clinical trials". In a lucid presentation, she explained the responsibilities of different stakeholders, sponsors in Clinical Trials and importance of documentation. In the post lunch session Dr. Mahesh Iyer & Dr. Ashiwini Mathur Novartis, gave hands on training related to clinical trials protocol & data treatment.

The third day of the Module -I was intiated by Dr. Dinesh Pillaipakkamnatt, Novartis and he invited Dr. Arun Patnaik, Novartis to deliver the 1st lecture on Overview of Clinical Data Management. He has discussed elaborately about the Data Management (DM) and its life cycle. Later he discussed about the challenges, responsibilities in DM while conducting a clinical trial. He ended with the presentation with a case report. Followed by Dr. Arun Patnaik, Novartis, Dr. Dinesh Pillaipakkamnatt, Head Analytics, Novartis has delivered his talk on Data Management Challenges-21CFR Part 11. On his talk he discussed about the importance of different technologies & software's used in data management. He covered various aspects related to challenges in data management and data capture systems. He also discussed about 21CFR Part 11 guidelines on electronic records and electronic signatures.

After the tea break, the session was started with the lecture by Mrs Archana Subramanyam, Head, Clinical development operations, GSK on Data management for Vaccine Studies. Archana began her talk by explaining how the Vaccine Clinical Trials (VCT) conducted and spoke about how the study has been performed on healthy population, safety issues and expected adverse events. She also discussed about the regulatory requirements in VCT. The session has been ended with panel discussion. The third day of the afternoon session started with workshop on Set up Conduct & Close out of clinical study by Dr. Dinesh Pillaipakkamnatt & his team, Novartis.

All the faculty and staff, NIPER students delegates were actively participated in the Module I and expressed that it is a rare opportunity for them to get exposed to this kind of conferences. And they informed that the Module -I is very informative about the drug discovery and pre clinical process. The delegates stated that they benefited a lot from the lectures given by the experts and also they stated that they really enjoyed the hands on experience session for the three days like preparing SOP, writing good clinical protocol etc.

In this Module-I, Dr. Ahmed Kamal, Project Director; Prof. N. Satyanarayana, Registrar; Course Coordinators NIPER-Hyderabad, Dr R. Srinivas, Dr S. Ramakrishna, Dr A. Krishnam Raju; Dr S. Sunitha (Convener); faculty members, Dr B Nagendra Babu, Dr N Shankaraiah, , Dr. T. Venu, Dr Narendra Kumar Talluri, Dr S. Gananadhamu, Dr. VGM. Naidu, Dr. Naveen Kumar, Dr. Md. Arifuddin , Dr. N. Satheesh Kumar; including senior faculty members Prof. V. Peesapati, Prof. Nalini Shastri and Shri M.S.N. Murthy, Shri C Badarinath and supporting staff of NIPER were involved actively and made this Module I as another successful event of NIPER-Hyderabad. In the Valedictory function, the Project Director of NIPER-Hyderabad has addressed the participants about the importance of attending such Conferences and how they are useful for their career. Valedictory function was ended with felicitation to Dr J.S.Yadav, Director, IICT on his demitting the office of director, IICT and concluded by Vote of Thanks.

Note: Schedule of Module-II (27th - 29th Sep, 2012)

NIPER-Hyderabad

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