



HYDERABAD

News Letter

DRUG DEVELOPMENT: CONCEPTUALISATION TO COMMERCIALISATION (D₂@C₂)

Module-3: Product Development, Analytical, IPR & Marketing (18th - 20th Oct, 2012)

A workshop on “Drug Development: Conceptualisation to Commercialisation” (D₂ @ C₂) Module-3 was organized by NIPER-Hyderabad with the support of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India and initiative was supported by Novartis, Hyderabad for knowledge sharing, during 18th - 20th Oct, 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 D₂@C₂ 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. The 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)

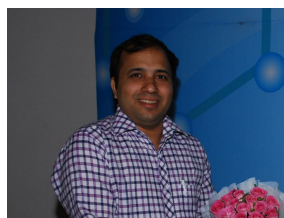
Module 3: Product Development, Analytical, IPR & Marketing (18th - 20th Oct, 2012)

Module 3 (Product Development, Analytical, IPR & Marketing):

The module 3 deals with how a new product launched in the market and how companies typically see new product development and commercialisation. Within the overall strategic process of product life cycle management will provide support from all phases of drug development, from early stage API method development to post-commercialization product and IPR issues.

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 in the Workshop.

Dr. R. Srinivas, Course Coordinator, NIPER Hyderabad, warmly invited the all the delegates & speakers for this module. He praised the organizing committee for the efforts in making the workshops with efficient speakers. Later on he made a note that analytical department are the backbone of all research areas. Dr. Srinivas concluded his welcome message by thanking Novartis for its help to organize current event and applauded all other members to enthusiastically take part in workshop and making the three modules a great success.



From Novartis side Dr. Sandeep, mentioned the importance of such workshops and conferences and he mentioned about how industry works and how the work will progress in industry. Dr. Kona Srinivas, Senior Director, Analytical Chemistry & CS group, Daiichi, Delhi has delivered a talk on “Product development & analytical development. He started

his talk by introducing Daiichi R& D centre. He has focused on preformulation and formulation aspects of product development. Role of analytical scientist in drug discovery process. Then he elaborated IND Documents, Part A & B. He concluded his talk by explaining some new formulations like Procardia XL, Controlled Drug Delivery- Depot, and Bone Implants etc.



It was followed by an excellent talk on “Impurity Profiling in Development of APIs” by Dr. R Nageswara Rao, Chief Scientist, IICT, Hyderabad, wherein he has briefed about drug safety, quality and efficacy. He explained the role of impurity profiling illustrating with elixir sulfanilamide, aspirin etc. Then he talked about genotoxic impurities, analytical challenges and its importance in discovery process. Finally he concluded that chromatography is an excellent means for monitoring of the starting materials intermediates and process reactions for controlling the purity of the final product in the discovery process.

Dr A.T. Bapuji, Vice President, Aurobindo Pharma, Hyderabad has delivered his talk on “Bioanalytical Method development and validation in drug development - special focus on BA/BE Investigations”. In his talk he discussed about significance of bioanalysis in drug development, regulatory and method development & validation by LC-MS/MS. He explained the different sample preparation techniques used for the bioanalysis study.





The first day of afternoon session was dedicated to give hands on experience on PK of NDDS profiles by Dr. Jagannath Kota and Mr. Parag Borde, Novartis, Hyderabad. All the delegates were divided into 12 equal groups and asked to give presentations. The participants were asked to study them, discuss among their team mates and present the information required.

The second day of the module 3 on Intellectual Property Rights. Dr. Mahindra, Dr. Reddys Laboratories, who gave a first talk on “Overview of patent Landscape”. He spoke about different types of Intellectual Property. He discussed about the legal rights, what can be patented and what cannot be patented with live examples. He also explained different role of Intellectual Property in generic as well as R&D drug industries in various countries like India, US and EU etc.



Ms. Meenu Wani, Patent Attorney, Ashland Chemicals, Hyderabad, delivered her talk on “IPR for pharmaceutical research careers. She explained the participants about the importance of IP and highlighted the difference types in IP. She elaborated different career choices in IPR. She concluded her talk with self assessment skill set and different certified courses available in India.

After session break, it was continued further by Dr. S. Padmaja, Managing Partner, iProPAT, Hyderabad, who has delivered a talk on “Strategies for Generic Drug Development”. She has started her presentation with generic product development, different strategy and road block of patent. She also explained about ANDA and DMF filing. She covered various aspects of patent and types of patents eligible for listing in Orange Book. In the post lunch session Dr. S. Padmaja, Managing Partner, iProPAT, Hyderabad, gave hands on training related to case studies on US and Indian patent laws, doctrine of equivalents and copyrights.



After the post workshop of second day, NIPER- H, organized cultural programmes. All participants are actively participated. Followed by dinner has been served for the delegates.

The third day of the Module - 3 on Pharmaceutical Marketing. Dr. Ratnakar, Dr. Reddys Laboratories, Hyderabad has delivered his first talk on "Promotion of Pharma Products". He discussed position of Indian market globally. Key drivers for new products, telemedicine & price control. Dr. Rohit Bhojraj, Head,



Commercial Operations, Novartis and he deliver the lecture on “Marketing Plan”. He has discussed elaborately drug development, patenting in relation with marketing. He discussed different key rolls to influence stakeholders and role of medical representative in pharma marketing.



After the tea break, the session was started with the lecture by Dr. Satyam Aneja, Global Brand Manager, Novartis on “Basics of Pharma Marketing”. He began his talk by explaining marketing process with suitable examples. He discussed about the Four P’s of the Marketing. He finally talked about strategies in marketing. The third day of the afternoon session started with hands on experience related to marketing a transplant product by Dr. Satyam Aneja and colleagues, Novartis.

All the faculty, staff, students delegates were actively participated in the Module 3. The delegates have expressed that it is a rare opportunity for them to get exposed to this kind of workshops. They informed that the Module -3 is very informative about the Product Development, Analytical, IPR & Marketing. The delegates stated that they enjoyed the hands on experience sessions for the three days like preparing in vitro & in vivo correlation, case studies etc.



In this Module-3, Prof. N. Satyanarayana, Registrar; Course Coordinators NIPER-Hyderabad, Dr R. Srinivas, Dr S. Ramakrishna, Dr A. Krishnam Raju, Dr N Shankaraiah; Dr S. Sunitha (Convener); faculty members, Dr B Nagendra Babu, 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 -3 as another successful event of NIPER-Hyderabad. In the Valedictory function, Dr R. Srinivas, Course Coordinator, NIPER-Hyderabad has addressed the participants and appreciated the organizing team. Dr. Ahmed Kamal, Acting Director, ICT & Project Director, NIPER- H in his message, appreciated the efforts made by NIPER- H and the academic support by Novartis, Hyderabad for successfully conducting this type of workshops. The D₂ @ C₂ of Module-3 was concluded by Vote of Thanks.

NIPER-Hyderabad

National Institute of Pharmaceutical Education and Research
(Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India)
Bal Nagar, Hyderabad, A.P. – 500037, India. Ph: 040-23073741/40

www.niperhyd.ac.in