HYDERABAD

News Letter
DRUG DEVELOPMENT: CONCEPTUALISATION TO COMMERCIALISATION (D_2@C_2)

Module-2: Medical Writing, Regulatory Affairs & Pharmacovigilance (27th - 29th Sep, 2012)

A workshop on "Drug Development: Conceptualisation to Commercialisation" (D_2 @ C_2) Module-2 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 27th Sep – 29th 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. 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 2 (Medical Writing, Regulatory Affairs & Pharmacovigilance):

This model focused on the latest challenging area of medical writing, regulatory affairs and pharmacovigilance. India is becoming the hub for these particular areas, so understanding of the core is utmost essential for students and others to excel themselves in these areas. Documentation is an important part of research as it helps researchers to express their results in public domain. Second module of this conference started with the same goal of providing knowledge in the relevant areas and helping them to develop publishing and documentation skills.

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.

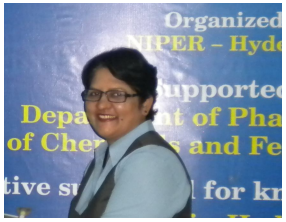
Dr. R. Srinivas, Course Coordinator, NIPER Hyderabad, welcomed the gathering and in his welcome address, highlighted the objective of the present module and demonstrated the recent developments of Pharmaceutical Sciences and highlighted its role in current scenario. And also he mentioned that the drug discovery process is a highly dynamic and rapidly growing. 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 two modules a great success.

From Novartis side Dr. Amit Khanna, Group Head, Global Regulatory CMC, focused on the importance of such workshops and conferences and he mentioned that it will help the students to update themselves in the field of the drug development. He emphasized the importance of hands on training in a workshop like this rather than a conference. And also he mentioned the key objective of this workshop was new advances of global drug development and several elements of whole complex drug discovery process. Later he appreciated NIPER, Hyderabad and Novartis for successfully organizing the first module of the workshop. Dr. Priyadarshini Roy, Novartis has delivered a talk on "Medical writing as a profession – Key skills, Qualification and Future Prospects". In her talk, she focused on concepts like what is Medical writing, various types of Medical writings and its role in drug development. Then she elaborated Medical writing as a career, with an insight of her own background. It was followed by an excellent talk on "How to write a research publication – Views from an editor" by Dr. Rao. Vadlamudi, Director St. Peters College of Pharmacy, Warangal, wherein he has briefed about the Research work and design for publication, Role of statistics in representing the results and elaborated how to write a scientific paper. He concluded his talk by explaining the term called "Plagiarism" and highlighted the mistakes often committed by the authors.

Dr Mayur Kherdikar, Novartis has delivered his talk on "Overview of Regulatory Medical Writing". In his talk he discussed about Regulatory Medical writing, Types of documents and Target audience like EMA, ICH and US-FDA. He explained the clinical study protocols and other related reports, citing various ICH – Efficacy guidelines like E3

and E7 respectively. The first day of afternoon session was dedicated to give hands on experience on abstracts and posters writing by Dr. Priyadarshini Roy and her team, 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.

On the second day, Dr. Amit Khanna, Group Head, Global Regulatory CMC, Novartis commenced with his opening remarks about 2nd day activities like Genesis of Regulatory Affairs, Specializations in Regulatory Affairs. Dr. Shushil Choubey, MD, DRA site Head, Novartis, who gave a talk on "Global Regulatory Landscape". He spoke about Elements of landscape reformation and has pointed out that increased expense and productivity within Pharma industry is the driving force for globalization. He also explained different regulatory environments in various countries like US, EU, Japan, China etc.



Ms. Rajashri Ohja, Founder and Director, Raaj GPRAC, Mumbai, delivered her talk on "US-ANDA filing procedure as per CTD/e-CTD". She explained the participants about components of CTD and highlighted the basic difference between CTD and e-CTD. She concluded her talk with a few case studies like bioequivalence deficiency for an ANDA submission. After session break, it was continued further by Ms. Bharti Khanna, Delhi, who has delivered a talk on "Emerging Trends in Regulatory Affairs". She has pointed out that Global Pharmaceutical market was estimated at US $ 955.5 billion in 2011. She explained in an excellent way the evolution of the regulations by illustrating the thalidomide tragedy. She also explained the participants various regulations like licensing etc., and has concluded her talk with emerging trends in regulatory affairs. In the post lunch session Dr. Sachin Wani/Mr. Syam Musuvathi, Novartis and Ms. Rajashri Ohja, Founder and Director, Raaj GPRAC, Mumbai, gave hands on training related to review of product labels in line with CTD Sections.

The third day of the Module -2 on Pharmacovigilance was initiated by Dr. Rajesh Ghosh, Novartis and he invited Dr. Promit Roy, Novartis to deliver the 1st lecture on History and Evolution of Pharmacovigilance. He has discussed elaborately about the importance of Pharmacovigilance. Later he discussed about the adverse drug reaction, serious adverse event, Key Partners in monitoring safety of medicines and safe drug. He ended with the presentation with some examples of serious and unexpected ADRs. Followed by Dr. Shoba Rani,

Al Ameen College of Pharmacy, Bangalore has delivered her talk on identification and reporting of adverse drug events. In her talk she discussed elaborately about Epidemiological Methods and their importance. She covered various aspects related to adverse drug events with examples. She also discussed about essential components of an ADR Report, Functions and outcomes of the WHO Programme for International Drug Monitoring.

After the tea break, the session was started with the lecture by Dr. Sibin Kurien, Novartis, on Analysis and reporting of the Adverse events. He began his talk by explaining about adverse events and sources of adverse Events with suitable examples. He finally talked about signals and purpose of signal detection.

The third day of the afternoon session started with workshop on Pharmacovigliance Case processing Assessment and medical analysis by Dr. Mangesh and Colleagues, Novartis, Hyderabad.

All the faculty, staff, students and delegates were actively participated in the Module 2. 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 -2 is very informative about the Medical Writing, Regulatory Affairs & Pharmacovigilance. The delegates stated that they enjoyed the hands on experience sessions for the three days like preparing dossiers, writing abstracts and posters & case studies etc.

In this Module-2, 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 -2 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, IICT & 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 D_2 @ C_2 of Module-2 was concluded by Vote of Thanks.

Note: Schedule of Module-III (18th - 20th Oct, 2012)

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