

An Insight into Biopharmaceuticals- Technologies, Analysis and Regulatory Issues 25 June to 7 July 2012

25 -28 June 2012: Department of Pharmaceutical Quality Assurance

25-06-2012: New week, new QIP, new participants and new speakers! The first day of the programme was enlightening as both the talks set an appropriate tone for the deliberations to follow for the next two weeks. The programme started with a talk on “Biosimilar regulations” by Mr. Singaravelan (DGM Regulatory Affairs, Mylan Laboratories, Hyderabad). He talked about the regulatory scenario of world over in a lucid yet informative manner and sliced through this complex topic well. The second talk of the day was delivered by Dr. Prashant B Musmade (Assistant Professor, PQA), who spoke on pre-clinical pharmacokinetics. He explained the practice of preclinical pharmacokinetics with his hands-on experience. In the afternoon session, there was a demonstration on biological sample preparation using various techniques.

26-06-2012: Dr. B S Muddukrishna (Lecturer, PQA, MCOPS) started with an interesting talk on “Challenges in biopharmaceutical analysis.” He elaborated on various challenges in analyzing the drugs in biological matrix, their applications and problem solving. Mr. S T Bhagawati (Research scholar, MCOPS) who spoke next dealt with “Oral strip technology- the next generation drug delivery system.” The lecture was a dialogue between the participants and the speaker with enthusiastic participation from the delegates. Mr. Syed Sajjad Hussein (Lecturer, PQA) was the next speaker. He spoke on “Nanopharmaceuticals in HIV therapy.” He elaborated on preparation, characterization and stability of nanopharmaceuticals with a few interesting real life examples. Dr. P C Jagadish (Assistant Professor) delivered a lecture titled “MS ionization techniques for biopharmaceuticals.” Mr. Muddukrishna and team demonstrated HPLC operations in the afternoon.

27-06-2012: Dr. S G Vasantharaju began the day with a talk “Chiral drug analysis.” He explained chiral drug analysis in a very simple way. Following this, Dr. Sudheer Moorkoth (Assistant Professor) with his lecture “Generics to biogenerics- the story demystified” gave very useful information. The third lecture for the day came from Mr. Swapnil J Dengale (Lecturer), which was titled, “Co-amorphous pharmaceutical.” He explained the basics and the significance of a new formulation technology. In the afternoon session, Dr. Vasantharaju and team demonstrated spectroscopic instruments and their operation.

28-06-2012: “Recent advances in separation sciences- an industrial perspective” was the title on which Mr. Arun Kumar N (Lab Manager, GE Global Research) spoke. That was the first lecture of the day. That was followed by a talk from Mr. Amitav Ghosh (Scientist, Ecron Acunova) on “Matrix effect in bioanalysis” with case studies and theoretical background. He apprised the audience the serious implications of overlooking the vital characters of matrices in bioanalysis. The practical aspects of GCMS and DSC were demonstrated under the supervision of Dr. Sudheer Moorkoth.

29 June - 3 July 2012: Department of Pharmaceutical Biotechnology

29-06-2012: The first day began at 9 am with a lecture by Dr. V. M. Subrahmanyam (Professor, DPBT) on “Large Scale Production of Biopharmaceuticals.” He outlined the various issues involved in the production of biopharmaceuticals on large scale such as scale up, design etc. This is followed by another lecture on “Biopharming” by Dr. Jesil Mathew A (Asst. Professor, DPBT). He explained in a lucid way about various expression systems and the advantages of cultivating plants for production of biopharmaceuticals. Dr. P. Vasanth Raj (Asst. Professor, DPBT) spoke on Gene Therapies, an emerging and exciting area in combating various genetic disorders.

30-06-2012: Dr. Sam T. Mathew (Process Head, Medical Writing, Accenture, Bangalore) delivered a talk on Medical Writing, where he dwelt at length on the intricacies of medical writing as well as the art of writing. He encouraged the participants to take up medical writing as a career option. Second speaker of the day was Ms. Ann Mary Joy (Senior executive (QA), Biocon, Bangalore), who is an alumna of MCOPS. Apart from giving the overview of the company, she explained about the largescale production and analysis of Biopharmaceuticals as well as the regulatory aspects. Her rich industrial experience and expertise helped the Post Graduate students of the department to understand the Industrial set up. The morning session was wound up with a talk on “Cytokines as Biopharmaceuticals” by Dr. N. Sivagurunathan (Asst. Professor, DPBT). He emphasized on the need of cytokines as biopharmaceuticals and provided the list of cytokines approved.

02-07-2012: A talk on “Biofilms and antibiotic resistance” by Dr. (Mrs) Atulya, Inspire Research fellow, DST marked the beginning of morning session. The various factors leading to biofilm formation and its role in antibiotic resistance etc., were explained. This talk was followed by a talk on adjuvants in vaccines by Mr. Venkatesh Kamath (Lecturer, DPBT), wherein he emphasized their effect on enhancing immunogenicity of vaccines. The last talk for the morning session was on immunological basis for vaccines by Mrs B. Meenashi Vanathi, Research Associate, (WOS- A, and DST). She discussed at length the importance of understanding the immunological basis with simple illustrations for designing effective vaccines.

03-07-2012: The morning session on day 4 began at 9 am with a lecture on “Nanobiotechnology in drug delivery systems” by Dr. Bharath Rajguru, Associate Professor, Dept. of Biotechnology, MIT, Manipal. He explained in a lucid manner the intricacies in delivering the effective doses of drugs to difficult sites such as vitreous humor to treat macular degeneration with simple yet effective illustrations. Dr. Balaji, Asst. Professor, Dept. of Biotechnology, MIT, Manipal, followed it up with a talk on “Bioinformatics in drug discovery.” He elaborated on the usefulness of various computational tools in drug designing and discovery. Last talk of the session was by Mrs. Angel Treasa Alex (Lecturer, DPBT), on “Delivery of drugs to brain: Challenges and strategies.” The clear explanation on the anatomy of brain and BBB through pictorial representations helped the participants to understand the challenges in delivering drugs to brain.

Afternoon sessions on all days were devoted to laboratory demonstrations on biotechnological tools and experiments, where the participants were given hands-on experience. Credit is due to Mr. K. Narayanan and Mr. Hitesh Jagani, Research Scholars, under structured Ph D Program of Manipal University for the smooth conduct of these.

Mr. Venkatesh Kamath and Mrs. Angel Treasa Alex compeered the sessions on all the four days. Dr. J. Venkata Rao, Professor and Head of the Department supervised the entire programme.

04 -07 July 2012: Department of Pharmacy Management

04-07-2012: Two talks were scheduled on 4th July 2012 for forenoon session. The talks were delivered by Mr. Girish Thunga, Department of Pharmacy Practice, MCOPS Manipal and Mr. Kanav Khera, Department of Pharmacy Practice, MCOPS Manipal. Mr. Thunga apprised the participants about newer avenues in poisoning management. He spoke about how new treatments are emerging in treating poison cases that are seen in Hospital. Mr. Khera spoke about patient reported outcome measures where he briefed participants on importance of outcomes research for making informed choice of treatment. The afternoon session was for health check up camp. The participants underwent health checkup which was done by Mr. Anil TM, Research Scholar, Department of Pharmacy Management, MCOPS.

05-07-2012: The next day Dr. Anantha Nagappa Naik, Professor, Department of Pharmacy Management, MCOPS, Manipal discussed the role and importance of pharmacists in community setup. He also briefed the participants about pharmacoeconomics. Ms. Swapna S, Faculty, KMC IC spoke on importance of Patient Safety. She highlighted that importance of patient safety is of paramount in healthcare. In the afternoon session participants were oriented to various associations such as Association of Community Pharmacists of India, International Society of Pharmacoeconomics and Outcomes Research (ISPOR) – South India Chapter and the activities carried out in MCOPS.

06-07-2012: The third day started with talk by Mr. Anil TM. He spoke on Biopharmaceuticals – Cost Benefit Analysis. This was followed by a talk by Dr. Manthan D Janodia, Assistant Professor, Department of Pharmacy Management, MCOPS, Manipal. He talked on IPR and Biopharmaceuticals. The afternoon session

was dedicated for visit to various departments of MCOPS for QIP participants where they were shown facilities and research work of various departments of MCOPS.

07-07-2012: On July 7 a series of lectures were planned throughout the day as a part of Consortium of Progressive Pharmaceutical Associations of Manipal.

Report: Dr. Krishnamurthy Bhat, Dr. J Venkata Rao, Dr. Manthan Janodia and Dr. N Gopalan Kutty