**AICTE Sponsored QIP**

on

**‘FORMULATION AND MANAGEMENT OF QUALITY MEDICINES’**

Organized by Departments of

Pharmaceutics, Pharmaceutical Quality Assurance and Pharmacy Management

September 12-24, 2016

**REPORT- September 12-15, 2016(from Department of Pharmaceutics)**

A 13 day AICTE sponsored Quality Improvement Programme was organized jointly by the Departments of Pharmaceutics, Pharmaceutical Quality Assurance and Pharmacy Management of Manipal College of Pharmaceutical Sciences from September 12-24, 2016.

The lectures on the first four days were organized by the Department of Pharmaceutics. The programme was inaugurated by Dr. Narayana Sabhahit, Registrar, Manipal University in the presence of Dr. C. Mallikarjuna Rao, Principal, MCOPS and Dr. M. Sreenivasa Reddy, Vice-Principal, MCOPS. The event had participants from various colleges across the country including the faculty from MCOPS. The theme of the QIP was on ‘**Formulation and Management of Quality Medicines’** where the talks were delivered by experts from Pharma industry and faculty of MCOPS.

The resource persons emphasized on the use of Quality by Design approach in obtaining quality medicinal products. Along with this, a brief insight was also given on the various aspects of packaging, the use of Raman spectroscopy in quality control of topical products and the application of dendrimers in nanomedicine. The importance of phase diagrams in optimizing the formulation and various challenges faced in preclinical formulation development were the other areas which were touched upon by the speakers.

The equipments used in the formulation and analysis were demonstrated in the afternoon sessions by the faculty members and the research scholars from the Department of Pharmaceutics.

**Dept of Pharmaceutical Quality Assurance**

Report of Quality Improvement Program 16th September 2016 to 20th September 2016

16.09.16

The day opened with a talk on “Drug Product Dossier requirements of United States, Europe and India” by Mrs. Rajani Karpur, Deputy General Manager, Dossier solutions and services Pvt. Ltd., Bangalore. She spoke on the finer details of dossier requirements. She made a factual comparison of dossier requirements of regulated market spruced with her own rich experience. Second talk of the say was by Mr. Kedarnath S. A. Head, Formulation Development Nuwill Pharmaceuticals, Bangalore, on “Product Development by Quality By Design (QbD) approach”. Mr. Kedarnath explained the basics of quality of the product, parameters to measure linking them seamlessly to the design concept, resulting in regulatory compliant document. Afternoon session was dedicated for the hands on training in Gas Chromatography and High Performance Chromatography by teachers and research scholars of the Department.

17.09.16

This day witnessed a very interactive and thought provoking talk by Mr. Naveen Durishetti, Senior Executive, Quality Assurance at Lupin Limited, Goa on “Failure Investigation”. Mr. Naveen lucidly explained the reasons and nuisances of product failure and the process of investigation with real life examples and practical solutions. Mr. Swapnil J. Dengale, Assistant Professor, Department of Pharmaceutical Quality Assurance, Manipal College of Pharmaceutical Sciences was the second speaker of the day. He spoke at length about “Insitu and Exvivo methods in Pharmacokinetics. Starting with the basics of what body does to the drug, Swapnil graduated to the methods of pharmacokinetics, explaining the hands on techniques in invivo and invitro PK studies. Later part of the day, participants were taught the operation, precautions and routine maintenance of high performance liquid chromatography.

19.09.2016

First talk of the day was by Dr. Archana Kamath, MD (Ayu.), Sr. Product Manager, Medical Department, Green Chemistry Remedies, Udupi on the topic “Development and Standardisation of herbal formulation – an ayurvedic perspective”. Dr. Archana explained various types of Ayurvedic preparations citing original Sanskrit shlokas. She went on to explain the traditional standardization methods correlating them excellently to the modern standardization techniques.

Second talk of the day was by Mr. Raghavendra – Manager Global quality, Mylan Laboratories, Hyderabad on the topic “Evolution of GMP, Quality, Quality is growth”. Mr. Raghavendra explained about quality in Pharmaceutical companies and its impact on products with the help of beautiful audiovisual slides. He also talked about implementing GMP in each stage of operation and its outcome on the final product.

Afternoon was dedicated for the demonstration and usage of LM – MS/MS. This was diligently carried out by Ms Elizebeth Mary Mathew – Research Scholar of the Department under the guidance of her mentor Dr. Sudheer Moorkoth.

20.09.2016

Dr. Zainul started with basics of IR spectroscopy and then elaborated on NIR and FIR – the mechanisms of excitation, its Pharmaceutical applications and working of the instrument and data interpretation. The next talk was by Dr. Mangesh Vetal, Product Specialist atomic spectroscopy on “Advances in multielemental analysis”. Mr. Mangesh’s talk was an enlightening discussion on the methods available for analysing various elements. Comparing the latest developments in elemental analysis with conventional methods, Mr. Mangesh described high throughput, high sensitive multielemental analysis. Mr. Bharatesh S. Bhat conducted a very lively and informative interactive session on chromatography. Many doubts of the participants were clarified with real lab situations and practical insights. The day ended with a virtual demonstration of FTIR.

**QIP Report**

**21-24 September 2016, Department of Pharmacy Management**

On 21st September, 2016 Dr D Sreedhar, Head, Department of Pharmacy Management gave a brief overview of the lectures and sessions planned. Dr Manthan D Janodia, Associate Professor, MCOPS, Manipal was the first speaker. He gave a lecture on Intellectual Property Rights and Technology Transfer. Dr Rajasekharan Pillai, Professor, School of Management, Manipal spoke on Economic Evaluation of Healthcare Intervention. Afternoon session was on how to do a Patent Search by Dr Manthan.

Dr HG Joshi, Professor, School of Management was the first speaker on 22September, 2016. He delivered a lecture on Social Entrepreneurship. Next lecture was on “Healthcare delivery system in India – challenges and Opportunities” by Mrs Usha Rani, Assistant Professor, Department of Public Health, Manipal. Lastly, Dr D Sreedhar briefed about the Regulations pertaining Pharmaceutical Education and Research. Afternoon session was taken by Dr Sreedhar on decision making.

On 23rd September, Dr Virendra Ligade, Assistant Professor (Selection Grade) spoke on “Drug Brand Names”. Dr Uday Venkat, Assistant Professor, NITTE College of Pharmacy dealt with Evidence Based Practice. Ms Vijayalaxmi, Advocate, Udupi had brought about interesting cases related to pharma profession in her excellent lecture on “Pharmaceutical Legislations in the context of the Indian Judicial System”. Afternoon session was conducted by Dr Virendra Ligade, where he enlightened participants of the programme on how to evaluate pharmaceutical advertisements.

On the final day i.e on 24th September, Dr Raveendra Rao, Professor, School of Management, Manipal, have explained the details on pricing strategies followed by a lecture on “Role of Pharmacoeconomic Research in Healthcare” by Dr Pradeep, Assistant Professor (Selection Grade). Dr Pradeep later dealt with an interested activity on personality assessment. There was a brief lecture on “Herbal and Allopathic medicines – A comparative evaluation of quality Standards” by Mrs Bhavana Bhat. Certificates were distributed by Principal to all the participants of the program. A few delegates have volunteered and gave a feedback on the two-week program.