

CSIR- National Chemical Laboratory (CSIR-NCL), Pune organized an Interactive Session with Central Drugs Standard Control Organization, Mumbai and Indian Pharmacopoeia Commission (IPC), Ghaziabad and representatives from the regulatory bodies, academia and industry on October 11, 2017.

Dr. G. N. Singh, (DCGI) & Secretary-cum-Scientific Director, IPC in his keynote address said that research should be translated to drug discovery. He talked about the drug regulatory practices, roles of IPC highlighting the importance of the regulatory structure of drug research. He said “We (academia-industry-regulators) should work as a team and contribute effectively for the benefit of the common people”. He further said that we have to come out of our compartments and resolve the issues together that are relevant for the Society and Nation.

Dr. Pallavi Darade, Commissioner, Food and Drug Administration (FDA), Maharashtra spoke about the achievements of the IPC highlighting its policies regarding clinical trials. She informed about the significant contributions made by the various divisions of the Maharashtra FDA. She said that massive awareness campaigns are needed to be organized.

Dr. K. Bangarurajan, Dy. Drug Controller (India), CDSCO, West Zone talked about the recent regulatory updates in implementation of drugs and cosmetics acts. Dr. P. L. Sahu, Pr. Scientific Officer, IPC talked about the Role of IPC and current practices followed. Dr. K Raghu Naidu, Head Sitec Labs (P) Ltd., Mumbai spoke on the Challenges in Clinical Trial & Bioavailability/Bioequivalence Studies. Dr. Bobby George, VP & Head Regulatory Affairs, Reliance Life, Mumbai touched upon the subject ‘Regulatory Requirements for Bio-Similars & Stem Cells’.

On this occasion, CSIR-NCL and IPC signed an MoU for the joint research collaboration by combining their respective capabilities in the area of ‘Synthesis of impurities of API standards as per requirement of IPC.’

During the interactive sessions two panel discussions were conducted. The first panel discussion comprised of the regulatory bodies including Dr. G. N. Singh (DCGI)& Secretary-cum-Scientific Director, IPC, Prof. Ashwini Kumar Nangia, Director, CSIR-NCL Dr. Raman Mohan

Singh, Director, CDTL, Mumbai, Dr. K. Bangarurajan, Dy. Drug Controller (India), CDSCO, West Zone, Dr. P. L. Sahu, Pr. Scientific Officer, IPC, Shri. O. S. Sadhawani, Joint Commissioner, FDA, Nashik Division and Shri Kale held in morning.

In the afternoon session, another panel discussion was carried out which included leaders from industry and academia including Dr. K. Raghu Naidu, Sitec Labs Ltd., Mumbai, Dr. Bobby George, Reliance Life Sciences, Mumbai, Dr. Sudhir Pawar, LTM Medical College & General Hospital, Mr. Ravi Sekhar Kasibhatta, Lupin Limited, Lupin Bioresearch Center, Dr. Mukund Gurjar, Emcure Pharmaceuticals Ltd., Dr. Mahesh Burande, Institute of Pharmaceutical Education & Research, Pune, Dr. Chandra Vishwanathan, Regenerative Medicine.

Earlier, Prof. Ashwini Kumar Nangia, Director, CSIR-NCL introduced the idea behind the interactive session and gave the welcome remarks. Dr. Srinivasa Reddy coordinated the program.

It was one of the rare occasions where people from industry, academia and regulatory authorities came on one platform to discuss and understand issues of each other. Several participants appreciated the program theme to engage lively discussion among the stakeholders.



Prof. Ashwini Kumar Nangia and Dr. G. N. Singh exchanging the MoU documents



Dignitaries present for the panel discussions

