

## Report of the Faculty Development Programme

1st to 12th July, 2019

A faculty development programme was organized from 1st to 12th July, 2019 at Biocon Academy, Bangalore. Biocon Academy introduces Faculty Development Program (BA-FDP), a first-of-its-kind initiative to empower Biotech Faculty from various educational institutes by helping them upgrade their knowledge of emerging industry-specific technologies. This 2-weeks full-time program, delivered at the Biocon Academy, includes classroom sessions with Subject Matter Experts (SMEs) from Biocon as well as industry assignments and training at Biocon's state-of-the-art labs. The course has been designed to expose academicians to the latest equipment, technologies and processes being deployed by the industry. The course comprises of 22 interactive lectures delivered by SMEs from Biocon and 32 hours of experiential learning at Biocon's high-end and world class manufacturing facilities, quality and research labs. There were 20 number of participants registered for this programme from different Universities across India and Malaysia.



**Participants of Biocon certificate Program in Faculty Development**

## INAGURAL SESSION

The esteemed dignitaries' personalities present on the dais in inauguration of the programme:

- a) Ms. Bindu Ajit, program Director, Biocon Academy
- b) Dr.MS Rama Krishnan, Vice-President R&D, Biocon
- c) SS. Easwaran, Dean, Biocon Academy
- d) Anjali Nath, Manager-QA, Biocon
- e) S.Ramgopal, Director, Biocon Academy

Ms. Bindu Ajit, program Director, Biocon Academy had delivered the welcome note. Dr.MS Rama Krishnan, Vice-President R&D, Biocon has inaugurated the program and in his inaugural address, Dr.Rama Krishnan has enlightened the faculty participants about nurturing the students in accordance to requirements of biopharmaceutical industries. SS. Easwaran has given overview of Biocon park, campus and academy. Anjali Nath has stressed upon the fire and safety instructions to be followed during the functional visits at Biocon and finally S.Ramgopal has outlined the overview of the program schedule.

The first technical session was on the topic "Overview of life cycle of a drug and development" was delivered by SS.Easwaran and focussed on drug substance, drug product and its development stages in biopharmaceutical industry. After lunch, a topic on "Introduction to Biotech Market and segments, department in Biopharma and functions" was discussed by SS.Easwaran to enlight the participants to know about opportunities on biotech market with their recent developments. In another technical session by Dr.Prathima khandelwal, Professor&Head, Teaching Learning Centre, Global Academy of Technology, Bangalore, karnataka on "Creative Teaching Methodologies and Active learning strategies" and discussed on the changes in the teaching methodologies. The various competencies that need to be developed and the preparation required from the side of the teacher educators were discussed.

On day 2, Garima Mishra - Associate Scientific Manager of Molecular Biology and Cell Line Engineering Division (R&D) discussed on cell line selection and characterization in production of biologics. Her session also includes the need of cell line development and a case study on In-

house cell line development of B mab X. In the forenoon, we had an functional visit to Biocon park to get expose on the strategies that are being applied in cell line engineering division.

On day 3, Abdul Waheed - Associate Manager of MSAT enlightened the importance of mammalian cell culture over microbial cells. His talk also includes about the role of biopharmaceuticals, its sources, advantages and challenges in development of biopharmaceuticals. He also discussed on cell culture environment, types of bioreactors and its mode of operations. In the forenoon session we had an functional visit to Medical Devices block and learned about the insulin in a pen device, popularly known as glargen.



**Gathering of participants after the technical session**

On day 4, Ankur Bhatnagar - General Manager, R&D has enlightened on drug development and overview of monoclonal antibodies. He also shared his experience on working of biologics and its difference among the small molecule drugs. He also discussed about the role of mab's in treatment of cancer and it mechanism, the various drugs which are in investigation phase of clinical trials. In the forenoon session we had functional visit to Manufacturing-Biosimilars at Biocon Park for exposure of various fermentors.

On day 5, Dr.Sampath Srisailam - MSAT has discussed on bioprocess and bioinstrumentation role in pharmaceutical industry. He also discussed about various tools and equipment which are commonly used and functional flow of analytical department. He also enlightened the role of HPLC/UPLC in drug purification and also on peptide mapping. In forenoon session we had functional visit to Bangalore Bioinnovation Centre at Electronic City Phase-1, which is a Incubation centre formed in joint collaboration of KBITS and DBT. Here, we had exposed to various incubatees in the field of biology and pharmacy. The Centre caters to the broad areas of Life Sciences i.e, Healthcare (MedTech/ Pharma/Bio-Pharma), Agriculture, Food/ Nutrition, Industrial Biotechnology and Environmental Biotechnology.

On day 6, Unnikrishnan M from Quality Control Unit, Biocon has delivered the scenario of Biocon as today and emphasized about the ICH guidelines and regulations that are defined by DCGI and USFDA. he also discussed over the quality system, parts of quality unit, instrumentation and audits of pharma sector. In the next sessions of the day, Zacharia Mathew from Quality Control Unit spoke on product validation process and the role of equipment and methods that impact a product quality. He elaborated on the classification of instruments and the pathway that are used in industry for the proper functioning of the product. In the forenoon session we had an interactive functional visit to Quality Control Unit at Biocon park with Zach Mathew. He explained about the pilot scale operations and the quality audits of the monoclonal antibodies division at Biocon.

On day 7, Anjali Nath from Quality Assurance division of Biocon has delivered a lecture on Quality Management System policies, planning, resources, responsibilities and continual improvement. She elaborated the use of CI in quality assurance by emphasizing on four specific elements of the quality system, which are process performance and product quality monitoring, corrective action and preventive action, change management and performance of product quality. In the forenoon session we had a functional visit to QA division at Biocon Campus to get exposed on documentation process in the quality assurance division. We had an activity performed with the KAPA system to verify the documents by choosing various forms in the manufacturing products.

On day 8, Sujakaran from QC-Microbiology has delivered a lecture on the role of microbiologists in pharma sector. He elaborated on the design stages of process/product viz.

HVAC, water lines, drain and lab design. He also discussed about the proper growing practices, testing process, monitoring process and competent personnel. The next session was shared by Arava Muthan to discuss about OOS and failure investigations which play a vital role in biotech industry. He discussed about the OOS investigation which includes review of test data and review of production and extended laboratory testing. In the forenoon session we had an functional visit to QCMB division at Biocon park to learn the regular practices of microbiologist in the quality control unit.

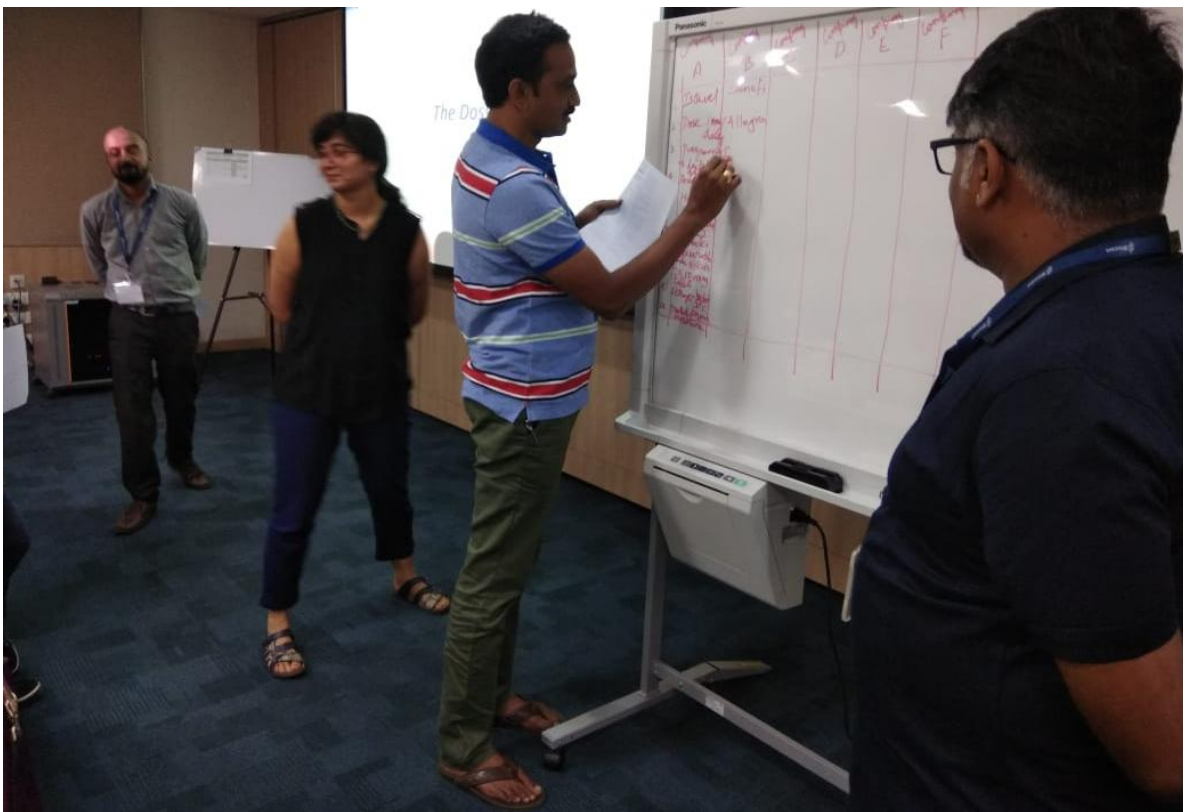


**Participants with proper growing practices at quality unit of microbiology division**

On day 9, Dinesh- Senior Scientific Manager of R&D has discussed over the biologics process development, clinical trial process, preclinical research, clinical research and life cycle of process development. He elaborated on the choosing of the host cell for clone development and its trouble shooting in the complexity of proteins. He also discussed on typical manufacturing process flow which includes from choice of vial to drug product processing and filling with the choice of mammalian cell culture. The next session was delivered by Ramgopal - Director of Biocon Academy on IP in biopharma and biotech that plays a crucial role for protecting the property of any biological product. He emphasized on the intellectual property rights to apply innovation, expertise and global reach to advance public health and improve people lives. In the forenoon session, we had functional visit to R&D department to have exposure on the types of bioreactors, scale down, scale up process and challenges in SDM.



On day 10, Srivatsa Rao QA - Biocon campus has delivered lecture on International Regulatory pathways with a activity to involve all the participants. He emphasized the role of regulatory affairs in the international market, their contribution, filing of data, document services and regulatory compliance. Dossier was given as a activity session for the participants to have an exposure of the documentation to be submitted for any product. The next session was delivered by Naresh Tondare on Indian Regulatory pathways and gave an glimpse of Indian system of licensing the products and how they differ from International property rights. He had an vast discussion on all implementing authorities in our country and their functions. He also discussed the role of state government bodies in the regulatory system by elaborating on SLA (State Licensing Authority) regulations. In the Fore noon we had an end session with Dr.Sandeep Athalye - Chief Medical Officer on clinical research which determines the safety and efficacy of medications, devices, diagnostic products and treatment regimens intended for human use.



**Dr.V.Praveen Kumar performing an activity of dossier in regulatory affairs**

## VALEDICTORY SESSION

Receiving an overwhelming response with participants, A two-week FDP on came to an end with valedictory session, graced by Ms. Seema Ahuja (Vice President and Global Head of Communications, Biocon Group), SS. Easwaran (Dean, Biocon Academy) S.Ramgopal (Director, Biocon Academy) and Srivatsa Rao (Manager - QC). Ms. Seema Ahuja in her valedictory comments stressed upon the the new methods of delivering lectures and also the importance of skilling courses. FDP was valedicted with certificates distributed to participants by Ms. Seema Ahuja and Ms. Bindu Ajit. On the whole the program received a lot of positive feedback from participants and it paved the way for participants to implement their Research Ideas in industrial sector.



**Dr.V.Praveen Kumar (right side) and Dr.GVS Rama Krishna (left side) receiving certificates from Ms. Seema Ahuja -Vice President and Global Head of Communications of Biocon Group**