

Report of the Faculty Development Program

17th June 2024 to 28th June 2024

A faculty development program was organized from 17th to 28th June 2024 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 industry. The course comprises 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 21 number of participants registered for this program from different Universities across India.



Participants of Biocon certificate Program in Faculty Development

INAGURAL SESSION

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

- a) Ms. Leena Mary, Senior learning specialist, Biocon Academy
- b) Dr. Chella Pandian Pitchai, Associate Vice-President, Biocon Biologics
- c) SS. Easwaran, Academic Dean, Biocon Academy
- d) Ms. Bindu Ajit, program Dean, Biocon Academy
- e) S. Ramgopal, Program Director, Biocon Academy
- f) Dr. Pratima Khandelwal, Founder, Flyhigh

Ms. Leena Mary, Senior learning specialist, Biocon Academy delivered the welcome note.

Dr. Chella Pandian Pitchai, Associate Vice-President R&D, Biocon has inaugurated the program and in his inaugural address. **SS. Easwaran** has given overview of Biocon park, campus and academy and safety measures to be taken in emergency situations. **Ms. Bindu Ajit** helped participants in getting to know each other with her icebreaking session and **S.Ramgopal** has outlined the overview of the program schedule.

On day one (17/06/2024), The first technical session was on the topic "**Overview of life cycle of a drug and development and its Development**" was delivered by **SS.Easwaran** and focused on drug substance, drug product and its development stages in biopharmaceutical industry. The post lunch, "Biotech Industry Market segments, departments and functions" was discussed by **S. Ramgopal** to enlighten the participants to know about opportunities in the 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.



Gathering of participants after the technical session

On day 2 (18/06/2024), **Nagaraja G** - Associate Scientific Manager of Molecular Biology and Cell Line Engineering Division (R&D) discussed on cell line selection and characterization in production of biologics. His session also includes the need of cell line development and a case study on In-house cell line development of B mab X. We had a break for 30 min. followed by a talk by **Ishwar Bajaj** on Fermenter and microbial fermentation in the forenoon, we had a functional visit to Bangalore Bio-innovation center, funded by state and central govts which aims in supporting bringing the research to translational level. The Centre caters to the broad areas of Life Sciences i.e, Healthcare (MedTech/Pharma/Biopharma), Agriculture, Food/ Nutrition, Industrial Biotechnology and Environmental Biotechnology.

On day 3 (19/06/2024), **Dinesh B**- Associate Manager of MSAT enlightened the importance of Bioreactor and mammalian cell culture. His talk also includes the role of biopharmaceuticals, its sources, advantages and challenges in the development of biopharmaceuticals. He also discussed cell culture environment, types of bioreactors and their mode of operations. Further, the second talk was on Biosimilars and MABs by **Dr. Ankur**



Participants at BBC (Bangalore Bio-innovation Center) visit- Dr. Veeranna, Head, BBC Bhatnagar and he threw light on the strategies involved in production of MABs along with striking features and differences between inventor product and a biosimilar. After the lunch break, we had a functional visit to R&D Labs-I and learned about the facilities over there. On day 4 (20/06/2024), **Partha P Hazara** - 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 its mechanism, the various drugs which are in investigation phase of clinical trials. In the forenoon session we had a functional visit to Manufacturing-Biosimilars at Biocon Park for exposure of various fermenters. Further, a talk on Analytical method development was given by **Dr. Harish V Pai** followed by an Industrial visit to **R&D Labs- II**.



Technical Session.



Participants at Bangalore Innovation centre

On day 5 (21/06/2024), **Dr.Sucharita Jayakar** - has discussed Formulation and Drug products. She discussed various tools and equipment which are commonly used in drug formulation. **Dr.**

Mayank Garg highlighted the significance of Technology transfer in the field of pharma and biopharma products. Post lunch, we had an opportunity to visit DS/DP (Drug substance and Drug Products) sites assisted by **Dr. Sachin Pandey**.

On day 6, (24/06/2024), **SS Easwaran** has delivered a lecture on Current Good Manufacturing practices (cGMPs) 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, **KB Manohar** from Quality Control Unit spoke on product validation process and the role of equipment and methods that impact 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 **medical devices Facility** at Biocon park and observed the process of insulin packing in the form of Pens by commercial name INSUPen.



Participants at Biocon Medical devices Facility (INSUPen manufacturing)

On day 7 (25/06/2024), **B Praveen Kumar** from Quality Assurance division of Biocon delivered a lecture on **Equipment Qualification**. He 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 another session by **Dr. Ravindra**, **Process and cleaning validation** was explained in detail to the participants. We had another session after a break on

Quality control Microbiology by **Archana Rana** and discussed the role of microbiologists in the pharma sector. She elaborated on the design stages of process/product viz. HVAC, water lines, drain and lab design. She also discussed the proper growing practices, testing process, monitoring process and competent personnel. Post lunch, we had an Industrial visit to Biocon park to observe the Quality control unit which was led by **Dr. Jackson**.

Participants at B1 Unit (Quality control)

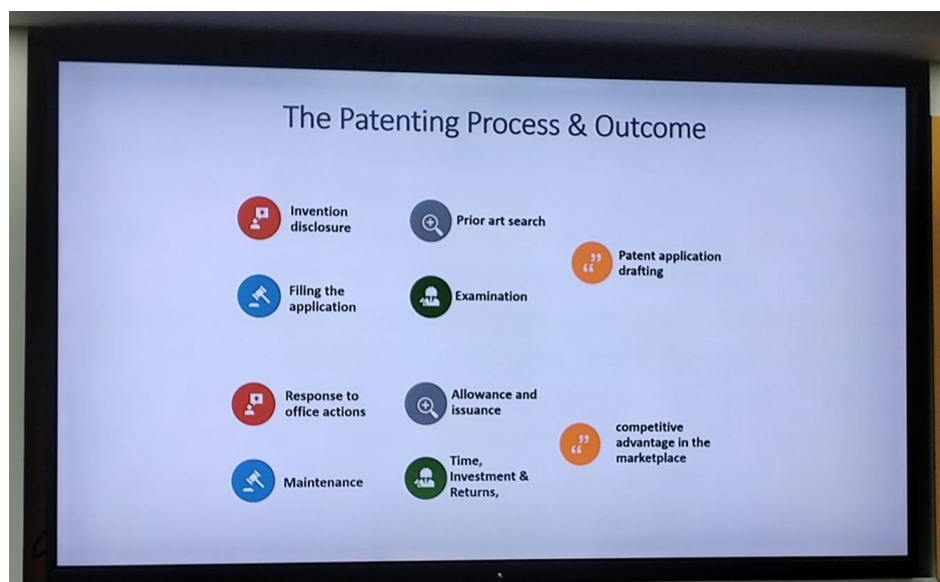
On day 8 (26/06/2024), **Dr. Suresh Kumar** delivered a lecture on **Quality management system**. The next session was by **Dr. Shibin** to discuss OOS, OOT and failure investigations which play a vital role in biotech industry. He discussed the OOS investigation which includes review of test data and review of production and extended laboratory testing. In the forenoon session we had a functional visit to Microbiology Quality control division at Biocon park to learn the regular practices of microbiologist in the quality control unit.



Hand on Experience on Handling HPLC and Mini Fermenter

On day 9 (27/06/2024), **Dr. SS Easwaran Dean Biocon academics** has discussed on **AI and ML in drug discovery**. 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 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 Dr. **Ramgopal** - on **IPR in biopharma and biotech** that plays a crucial role for protecting the property of any biological product. He emphasized intellectual property rights to apply innovation, expertise and global reach to advance public health and improve people's 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. Post T Break, **Suresh Kumar Chandrasekharan** delivered a lecture on **Quality management system**.



A session by Ramgopal on IPR in Pharma and Biotech industries

On day 10 (28/6/2024), **Yogender Reddy QA** - Biocon campus has delivered lecture on **National and 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. The dossier was given as a activity session for the participants to have an exposure of the documentation to be submitted for any product. 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. The next session was the ending session, and it was successfully delivered by **Dr. Sandeep Athyale** on **clinical development and Pharmacovigilance**. Post lunch, we had a walk through to Demo lab which was assisted by **SS Eswaran**, Dean Academics, Biocon Academy.

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 new methods of delivering lectures and the importance of skilling courses. FDP was validated with certificates distributed to participants by **Ms. Seema Ahuja and Ms. Bindu Ajit**. Overall, the program received a lot of positive feedback from participants, and it paved the way for participants to implement their Research Ideas in the industrial sector.



Dr. R. Gnanasekaran receiving certificates