JSS Academy of Higher Education & Research

JSS College of Pharmacy

Sri Shivarathreeshwara Nagara, Mysuru-570015

REPORT ON INDUSTRIAL VISIT

Faculty:

1. Dr. M P Venkatesh, Associate Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.
2. Dr. K Bangarurajan, Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.

Students:

- 2nd M. Pharm, Pharmaceutical Regulatory Affairs, Dept. of Pharmaceutics, JSSCP, Mysuru
- Ph.D. Scholar (Pharmaceutical Regulatory Affairs), JSSCP, Mysuru.

Dates of visit: 29th & 30th of July 2024

Day 1: 29th July 2024

Company: Biological E. Limited, Turkapally, Hyderabad

The industrial visit to Biological E Company, located in Turkapally, Hyderabad, was an insightful and educational experience that provided our group with a comprehensive understanding of the Biopharmaceutical manufacturing process.

Biological E Limited, established in 1953, is one of India's foremost biopharmaceutical companies, known for its pioneering efforts in vaccine and pharmaceutical product development and manufacturing. With a rich history and a commitment to quality and innovation, Biological E has established itself as a significant player in the global market, continually striving to improve healthcare outcomes worldwide.

Upon our arrival, we were warmly welcomed by the company's representatives, who provided a brief yet comprehensive history of Biological E Limited. Mr. Santosh Chandgadkar shared the company’s mission, vision, and the extensive range of products they manufacture mainly focused on the vaccines. This company is supplying 20% vaccines in global market.

Biological E Limited was the first vaccine company to get approved by US-FDA. They had wide range of accomplishments like viral, bacterial, yeast based and conjugate vaccine, and 10 Pre-qualification for supply of vaccines to WHO and several countries.

To ensure a detailed and organized tour, the participants were divided into groups: Group A, which toured the Quality Control Unit, and Group B, which visited the Production Unit.

Quality Control Unit Tour

During the visit to Quality Control (QC) unit, the sterile testing room, where products undergo rigorous testing to ensure they are free from contaminants is detailed. The importance of maintaining sterility throughout the testing process was emphasized.

The QC unit in charge elaborated on the different tests performed in the QC department, including *in vitro* tests and microbiological tests. We were also introduced to sophisticated equipment such as UV Visible Spectrophotometer, High-Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC), TOC Analyzer, stability chambers, storage rooms for culture storage and media storage, ELISA reader which are essential for conducting these tests. LIMS for the management of laboratory data for the compliance was briefly explained. The laboratories had grades for the clean room, after QC 1, we visited QC 2 which was microbiological testing laboratory for culture media. This tour underscored the critical role of quality control in the Biopharmaceutical industry, ensuring that every product released to the market is safe and effective.

Production Unit Tour

The next visit was to Production plant. Different processes involved in Biopharmaceutical manufacturing were detailed. The importance of adhering to stringent garment protocols to maintain a sterile environment, including wearing gloves, masks, hairnets, and gowns. Then production unit in charge explained the different stages involved, culture preparation, manufacturing and production. Later about the manufacturing grades within the unit—Grade A for high-risk operations like, Grade B as the background environment for Grade A activities, and Grades C and D for less critical stages in the manufacturing process and also detailed explanation of Upstream process and Downstream process and explained the process of cell culture, incubation.

Throughout the tour, the equipment's detailed in various steps involved, from raw material processing to final product packaging was discussed.

Warehouse Tour

Following a lunch break, both groups reconvened for a tour of the warehouse, The warehouse tour included explanations of the storage conditions required for different products, including strict temperature and humidity controls and even stress testing such as light exposure and Acid exposure and brief information about EMS and BMS system and how they operate by monitoring the temperature for storage rooms. Valuable insights into how the sampling is done below laminar air flow unit and how the BPR- Batch production record was discussed. The company manages its inventory, ensuring that products are stored correctly and shipped efficiently.

Q&A Session

The visit concluded with an interactive Q&A session, where participants had the opportunity to ask questions and clarify any doubts from various department heads. The company representatives provided detailed answers, enriching our understanding of the pharmaceutical manufacturing process and the company's operations. This session was highly beneficial, allowing us to engage directly with industry experts and gain valuable insights.

Conclusion

The industrial visit to Biological E Company was an enlightening experience that offered a comprehensive understanding of the inner workings of a top-tier pharmaceutical company. The practical exposure and in-depth explanations from the company representatives greatly enriched our knowledge and appreciation of the intricate processes involved in pharmaceutical manufacturing and quality assurance.

Acknowledgments

We extend our sincere thanks to Biological E Limited Company for their warm hospitality and for offering us such a priceless learning opportunity.

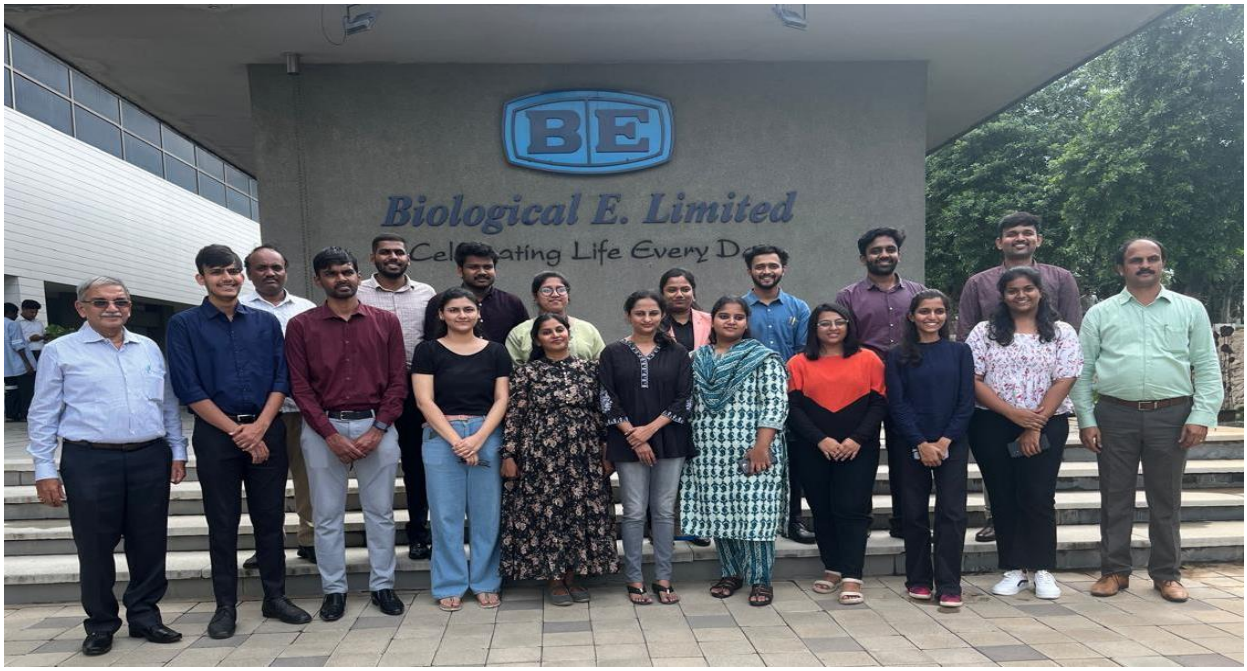

Fig 1: Students and faculty of JSS College of pharmacy at Biological E. Limited, Hyderabad

Day 2: 30th July 2024

Company - IKP Knowledge Park, Hyderabad

Introduction

We explored IKP Knowledge Park in Hyderabad, delving into the realms of innovation and entrepreneurship in life sciences, pharmaceuticals, and biotechnology. Our itinerary included an introductory session with Dr. Viswanadham Duppatla and guided tours of the USP monograph lab and the Analytical Lab, providing an in-depth view of IKP's role in supporting startups and advancing scientific research.

Session with Dr. Viswanadham Duppatla

The day kicked off with an insightful session led by Dr. Viswanadham Duppatla, Vice President, IKP who presented a comprehensive overview of IKP Knowledge Park and its mission. Dr. Duppatla emphasized IKP's position as a leading research park dedicated to fostering innovation and nurturing startups. He described how IKP functions as an incubator, offering essential resources, mentorship, and infrastructure to help startups flourish.

Dr. Duppatla shared real-life success stories of startups that have thrived with IKP's support, illustrating how IKP facilitates the entire startup development process, from ideation to commercialization. Through a combination of funding, mentorship, and access to state-of-the-

art facilities, IKP plays a crucial role in transforming innovative ideas into successful enterprises.

Tour of USFDA-Approved USP Monograph Lab

After the session, we toured the USFDA-approved USP monograph lab at IKP. This laboratory is vital to the pharmaceutical industry, focusing on developing and validating monographs essential for medicine quality control. The tour provided insights into the rigorous processes involved in pharmaceutical testing and validation, underscoring the importance of adhering to international standards to ensure the safety and efficacy of pharmaceutical products. This visit highlighted the lab's critical role in maintaining public health.

Visit to the Analytical Lab

We visited the Analytical Lab at IKP, which is equipped with advanced instruments and technologies for scientific research. We were introduced to various analytical instruments, such as Liquid Chromatography-Mass Spectrometry (LC-MS) and other sophisticated tools used for chemical analysis. The lab staff explained the applications of these instruments in drug development, quality control, and other research activities.

A notable aspect of IKP's Analytical Lab is its accessibility to startups and students on a fee-for-service basis. This model allows startups, which may lack the financial resources to invest in expensive analytical equipment, to access cutting-edge technology and expertise. By paying a fee, startups can conduct essential experiments, perform quality control checks, and develop their products without significant upfront investment in infrastructure. Additionally, students can use the lab for research projects, theses, or internships, gaining practical experience with advanced analytical techniques and bridging the gap between academic knowledge and real-world applications.

Conclusion:

The visit to IKP Knowledge Park was an enriching experience, providing a thorough understanding of the role of incubators in supporting startups and the importance of advanced analytical techniques in scientific research. The sessions and IKP tour offered a detailed look at how IKP contributes to innovation and excellence in the life sciences, pharmaceuticals, and

biotechnology sectors. The Analytical Lab's accessibility to startups and students further underscores IKP's commitment to fostering growth and education in these fields.

Fig 2: Students and faculty of JSS College of Pharmacy, Mysuru at IKP Knowledge Park,

Hyderabad

Acknowledgement: We thank Dr. T.M. Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru and JSS Academy of Higher Education and Research, Mysuru for providing an opportunity to visit the industry and providing a learning experience.