

REPORT ON INDUSTRIAL VISIT
TO
CLINSYNC CLINICAL RESEARCH PVT LTD
Date & Time of Event – 19th March 2022, 11:30 am

Industrial visit is important in the career of a student especially in professional degree. Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, College for Women, (Sponsored by The Exhibition Society) organized an industrial visit for M.Pharm students of all branches to provide an insight into the internal working of companies. ClinSync Clinical Research Pvt Ltd is a clinical research organization located in Madeenaguda, Hyderabad. The visit to the company is executed on 19th March 2022, at 11.30 am. About 14 M.Pharm students and 4 faculty visited the company on the day.

All the students and faculty reached the company at 11.20 am and registered the names at the reception area. We are instructed to place the phones in silent mode and then was accompanied into the company at 11.30 am. Dr. Sanjay Wajid, Head of Pharmacology department gave an introduction about the company. He explained briefly about pharmacology, importance of testing the drugs for safety and efficacy. Dr. Sanjay elucidated about comparison of test drugs with standard drug for generic drug development, different designs used for the study such as parallel design, crossover design in bioequivalence studies. He clarified that the company mainly conducts efficacy tests through bioequivalence studies in healthy human volunteers. He explained that the actual process of clinical research starts with collection of volunteers, their registration, taking consent from them, screening the volunteers for their health to check whether they are suitable for the study and prior informing them of the date of commencement of study.

Dr. Sanjay mentioned that on the day of study the volunteers will be explained about the study, risks involved during the study and their willingness for the study will be recorded visually with their sign, date and time. He further described that one day prior to the study the volunteers are given uniform, ID cards, subjected them to either 10 hours fasting study or fed study by giving high fat and high calorie food, administering the test, deciding the sampling points based on C_{max} and T_{max} and collection of blood sample after suitable intervals. He explained that any adverse event during the study should be treated whether it is related to the drug or not and

given compensation accordingly if any abnormalities or deaths occurs. Dr. Sanjay clarified that to conduct any procedure during the study standard operating procedures should be followed. We are then guided to different areas in the company such as volunteer registration area, volunteer waiting area, sample collection point, ECG room, Investigators room, ICU, Pharmacy, wards, bioanalytical area, dosing and vital station, sampling process area, storage area, washroom. Dr. Sanjay explained that all areas in the company have access control, ICU have 12 beds, wards have 160 beds and sodium monochromatic light fixed to check for any light sensitivity. He mentioned that the drugs come to the pharmacy, stored in controlled environment, placed in individual containers, collected from these containers when required. Dr. Mamatha, Dr. Praneetha, Dr. Harika clarified their queries with Mr. Sanjay after the session.

Mr. Pavan Kumar, junior executive of the company then took over the session to explain about Bioanalytical department. He explained about bioavailability and bioequivalence studies, pilot and pivotal studies. He then guided us to central sample storage area which consists of refrigerators where samples are stored at -20°C and -70°C . Then we are taken to sampling processing area consisting of BOD incubator, vortexer, cooling centrifuge, micropipette, repetitive pipette, nitrogen evaporator, balance room. Mr. Pavan took us to LCMS area which consists of different chromatographic equipment such as LCMS, HPLC and Mass spectroscopy. Sampling are being analyzed in the room by the personnel present.

Mr. Maddela Rambabu, Vice President of ClinSync Clinical Research Pvt Ltd also shared his valuable words with students and the faculty. He enlightened us with his different roles after completion of M.Pharm. He suggested students to complete PhD first and then work in any company. Mr. Rambabu stressed regarding the different opportunities in the field of Pharmacy after M.Pharm. He told the students to learn the work in any area from any person regardless of their qualification and do 100% to achieve big in future. Dr. Mamatha, Dr. Praneetha, Dr. Harika and Dr. Lavanya clarified their queries with Mr. Rambabu. Dr. Mamatha thanked Mr. Rambabu for giving the opportunity for the visit, enlightening the students with his words and guiding us throughout the visit. The session ended at 2.30 pm.

