CBCC Training report

A training session for Pharm-D 5th year students was arranged at CBCC Global Research Center, Ahmedabad. A batch of 6 students was trained from 9/Aug/2021 to 16/Sept/2021.

The training began with CBCC Orientation session by Ms. Anshika Sharma. It is an oncology and medical device focused Independent Contract Research Organization serving a wide spectrum of clinical research services including Phase I-IV clinical trial services, medical writing and HEOR related writing, ECG and image core lab services, post marketing registry trials to the Bio-Pharmaceutical, Medical device and Diagnostic companies. The vice-president of CBCC Global Research is Dr. Sandeep Singh. CBCC Global Research has more than 30 years of Clinical Research experience, partnered with more than innovator biopharmaceutical companies for over 100 clinical trial projects.

The training covered major five departments which includes Quality Assurance (QA), Clinical Operations (CO), Data Management and Bio-Statistics (DM and BS), Medical Writing (MW) and Clinical Pharmacology Unit (CPU). Students were posted for a week in each department.

Mr. Kashyap Gohil supervised the training, which included an overview of the departments, different designations and their roles and responsibilities, Regulatory Guidelines, and Standard Operating Procedures followed by each department.

Dr. Jignesh Patel delivered a session on "Designing Clinical Research," which was followed by a visit to the Clinical Pharmacology Unit. It provides a variety of clinical pharmacology studies to evaluate the safety, tolerability, pharmacokinetics (PK), and/or pharmacodynamics (PD) of an investigational pharmaceutical. The procedure from the beginning of the investigation, i.e. subject enrollment, through the end of the study was explained in an elaborative manner.

Following that, students were assigned to the QA department, where they were supervised by Mr. Kashyap Gohil and learned about ICH-GCP, ICMR, and NDCT regulatory requirements. There were other sessions on the history of clinical research, and drug sources. Ms. Fany Shah supervised the medical writing department, explaining several documents such as the Protocol, Investigational Brochure, Subject Diary, Informed Consent Form, Case Report Form, and Case Study Report. The contents of each document, as well as their rationale, were given.

Ms. Juhi Chavda provided training in the Clinical Operations Unit, explaining the many documents to be handled by the department as well as their duties and responsibilities. Proceeding with training program the last department where the students were posted was Data Management and Biostatistics falicitated by Ms.Tanu Sen. The data management process in clinical trials was explained starting from collection of data followed by review and reconciliation of data to locking and submitting the data. It also included different designations and their roles in data management.

The training ended with feedback and certificate distribution by Ms. Anshika Sharma. Overall this training was informative and interactive experience.

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