Aarupadai Veedu Institute of Technology

Vinayaka Mission's Research Foundation

Department of Biotechnology

The Department of Biotechnology, organized an industry expert talk on "**Bioequivalence Studies and its role in Drug Development** on 8.9.2026. The session provided students with an overview of the drug development pathway, including drug discovery.

Objectives of the Expert talk

- To enable students to understand the drug development process, including discovery, preclinical studies, clinical trials, and regulatory approval.
- To familiarize students with the different phases of clinical trials and their roles in establishing drug safety and efficacy.
- To teach students the principles and significance of bioequivalence studies for generic and reference drugs.
- To enhance students' knowledge of pharmacokinetics, pharmacodynamics, pharmacovigilance, and regulatory requirements.
- To raise awareness of ethical considerations and informed consent in clinical research.
- To provide insights into career and research opportunities in clinical research, pharmaceutical development, regulatory affairs, and bioequivalence studies.
- To strengthen students' industry-oriented knowledge and understanding of modern drug development practices.

The guest for the day welcomed by Dr.A.Nirmala, Professor and Head, Department of Biotechnology, AVIT. Followed by programme commenced with **drug development session** delivered by **Mrs.Gnanadeepa, Assistant Manager, Clinical Research & Bioequivalence studies, Micro-Therapeutic Research Labs, Chennai**. **Mrs.Gnanadeepa** talk focused on the session provided students with valuable insights into **the drug development pathway, including drug discovery, preclinical studies, clinical trials, regulatory approval and post-marketing surveillance**. Students gained insights into the different phases of clinical trials (Phase I–IV), focusing on safety, efficacy, dose optimization and long-term monitoring. The session also highlighted the significance of bioequivalence studies in establishing the comparable therapeutic performance of generic and reference drug products. Ensuring rigorous adherence to ethical standards and obtaining informed consent from all participants to protect their rights and well-being. Implementing robust data management and monitoring systems to ensure the accuracy, integrity, and confidentiality of trial data.

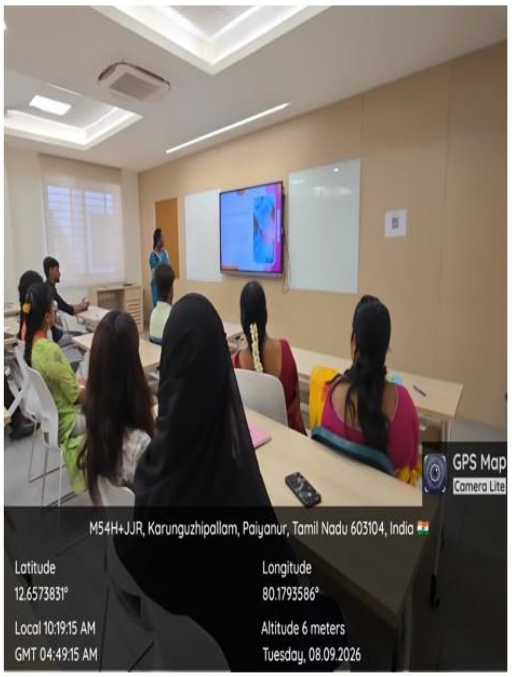
Special emphasis was given to the different phases of clinical trials. **Phase I** focuses primarily on safety, tolerability and pharmacokinetics;

Phase II evaluates preliminary efficacy and dose optimization and

Phase III assesses efficacy and safety in larger patient populations.

The session also highlighted **Phase IV/post-marketing studies**, which monitor the long-term safety and effectiveness of approved medicines.

EVENT GALLERY



The key concepts such as pharmacokinetics, pharmacodynamics, informed consent, ethics, regulatory requirements and pharmacovigilance were discussed. The programme enhanced students' understanding of pharmaceutical development and introduced career and research opportunities in clinical research, regulatory affairs, bioequivalence studies and pharmacovigilance with following key concepts

- To identify a potential therapeutic compound.
- To establish quality, safety and efficacy.
- To determine the appropriate dose and dosage form.
- To evaluate the benefits and risks of the medicine.
- To obtain regulatory approval before marketing.
- To monitor the safety of the medicine after approval.

The session facilitated students bridge theoretical knowledge with current industry practices and enhanced their awareness of career opportunities in clinical research, bioequivalence studies and pharmaceutical development. The programme concluded with a vote of thanks delivered by **Dr. A.Suganya,** Assistant Professor Grade-II, Department of Biotechnology, AVIT, who expressed

gratitude to the expert, faculty members, coordinators and students for their valuable contributions towards the successful conduct of the MoU-based activity.

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