



SANDIP FOUNDATION'S

SANDIP INSTITUTE OF PHARMACEUTICAL SCIENCES

At Post- Mahiravani, Tal/Dist. Nashik-422213, Maharashtra, India

Web: www.sips.sandipfoundation.org E-mail: info@sandipfoundation.org

Phone: (02594) 222591/92/93/94/95, Fax: (02594) 222555



SANDIP
FOUNDATION

Affiliated to Savitribai Phule Pune University, Approved by PCI, New Delhi, NAAC Accredited

Date: 02/02/2024

Zonal Championship Program on Drug Regulatory Affairs

Duration: 30 hours

Venue: Seminar Hall, Computer Department, SITRC, Nashik

Mode of Training: Offline

The Sandip Institute of Pharmaceutical Sciences, Nashik, under the umbrella of Sandip Foundation, hosted a 30-hour Offline Training Program on Drug Regulatory Affairs on January 30, 2024, in collaboration with Makeintern Zonal Championship and E-Cell IIT Hyderabad. This event catered to the academic needs of B. Pharm. and M. Pharm. students. Serving as the esteemed trainer for this program was Mrs. Razia Begum, currently holding the position of Senior Centralized Monitoring Lead at a Pharma CRO in Bangalore, India.

The inaugural session began with a warm welcome from Principal Dr. L. B. Borse, who provided insights into the institute and the students' keen interest in Drug Regulatory Affairs. Subsequently, Dr. Ganesh Shevalkar, the program coordinator, introduced Mrs. Razia to the participants. Following the introduction, Mrs. Razia delved into her extensive knowledge, sharing insights on various aspects of Drug Regulatory Affairs during her 30-hour offline training.

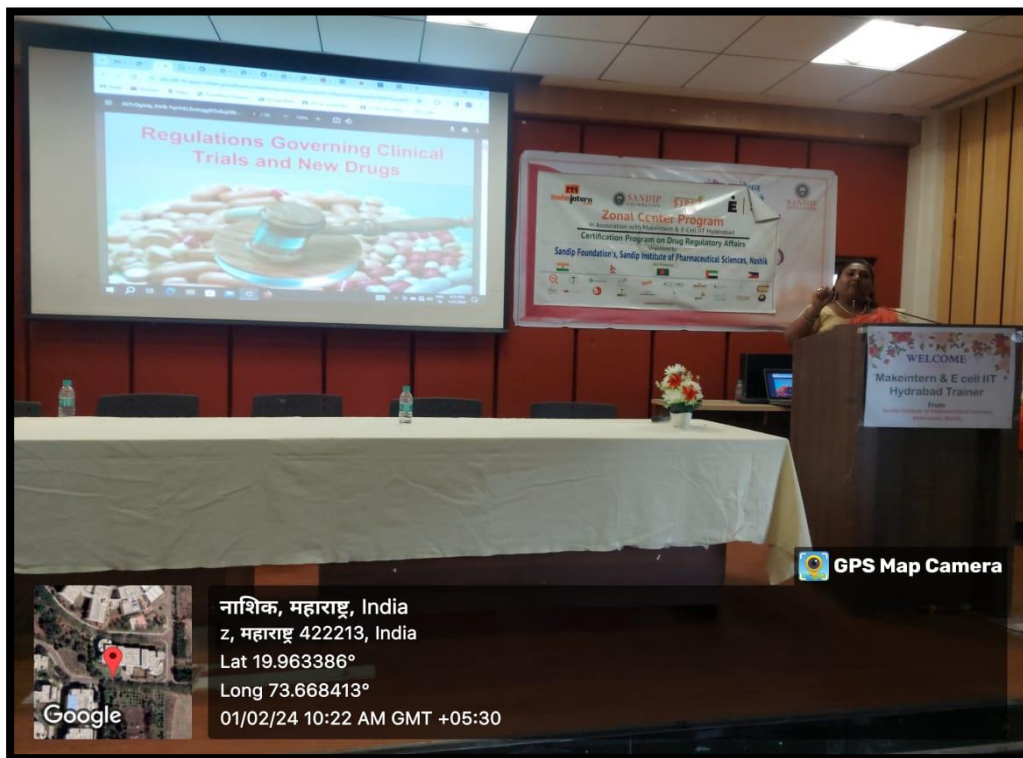
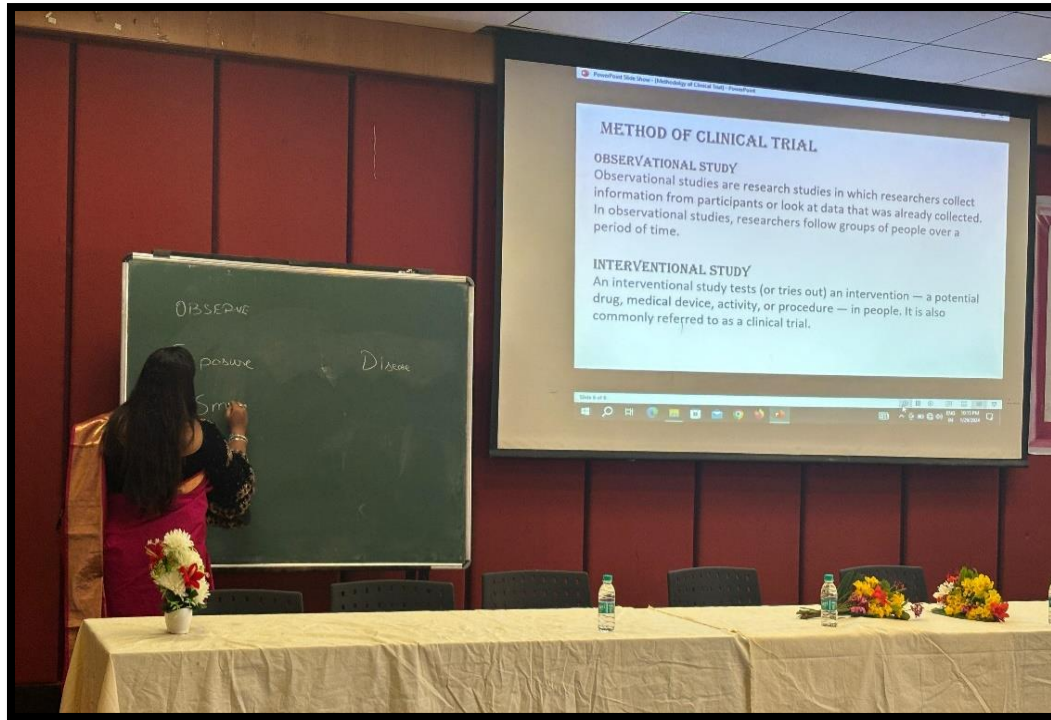
Throughout the program, Mrs. Razia engaged participants on diverse topics, including the Drug Development Process, ICH-GCP Guidelines, Clinical trial phases, Basic Fundamentals of Regulatory Affairs, Common Technical Documents - CTD (API and formulation), Introduction to eCTD, Regulatory Bodies, Quality Standards for Regulatory Compliance, ASEAN Common Technical Dossier (ACTD), Drug Approval Process, GLP, GMP, GCP, Regulatory application, and Career Opportunities.

An interactive session focused on interview preparation and career opportunities within the realms of Drug Regulatory Affairs and CROs allowed students to clarify doubts and express their interests. This program has proven beneficial for nearly 52 students. Following its completion, a comprehensive assessment was carried out for all participants, resulting in the selection of 5 candidates to represent the IIT Hyderabad zone in the finale. Dr. Shevalkar concluded the session by expressing gratitude with a vote of thanks.

Glimpses of the Zonal Program:











Dr. Ganesh B. Shevkar
Co-ordinator



Dr. Laxmikant B. Borse
Principal

