No.SDUAHER/KLR/R&D/ 312 /2024-25 **Date: 22.07.2024**

Event Report

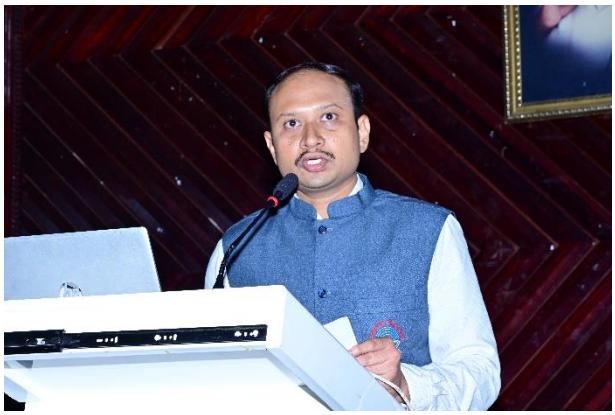
Name of the Event: "Workshop on Good Clinical Practice"

Department: Research and Development Cell

Venue: Sir CV Raman Auditorium, 3rd Floor, University Building, SDUAHER

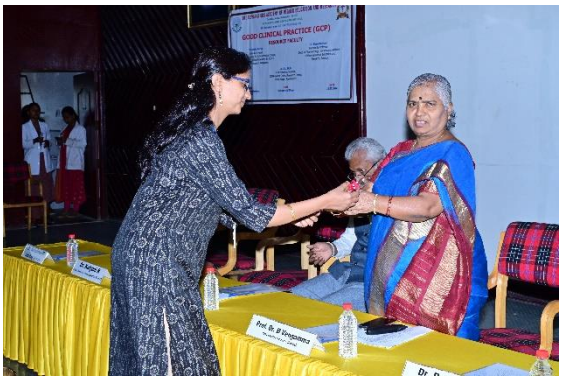
Date: 10.07.2024

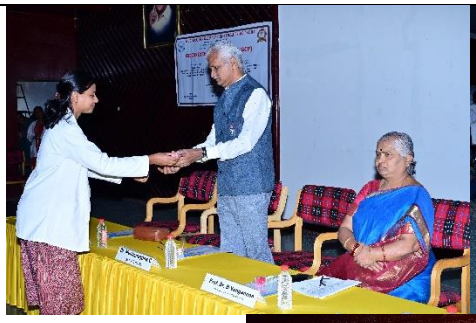
Sl. No.	Particulars
1.	**Introduction**: Good Clinical Practice (GCP) is an internationally recognized set of guidelines and standards for conducting clinical trials involving human subjects. GCP guidelines are established by the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use, specifically under the ICH E6 (R2) guideline. Adherence to GCP ensures that clinical trials are conducted ethically, safely, and scientifically, facilitating the development of new medical treatments and ensuring public trust in the research process. Considering the same Research and Development Cell of Sri Devaraj Urs Academy of Higher Education and Research, Kolar, Karnataka, India organized workshop on **Good Clinical Practice** on 10.07.2024
2.	**Proceedings:** **Inauguration**: Event commenced on 10.07.2024 at 10:00 AM with the invocation song by Mrs Suma & team. Compering was done by Dr. Shashidhar K, Deputy Coordinator, R & D Cell. All the dignitaries, resource persons have inaugurated the ceremony by watering the plant

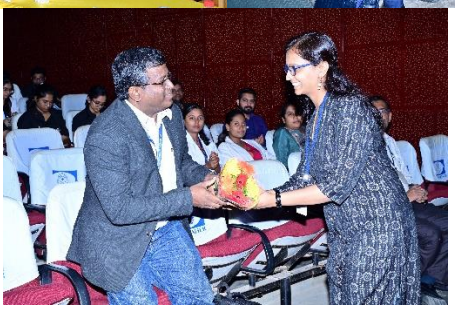


Welcome Address:

Dr. Kalyani R, Director, Research & Development Cell, SDUAHER, welcomed all the dignitaries of our institution, esteemed speakers and the participants of the event. with great pleasure she welcomed all for the workshop on Good Clinical Practice (GCP) saying active participation of all underscores a collective commitment to upholding the highest standards in our scientific endeavors. And briefed about GCP as an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human subjects. It ensures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data is credible.

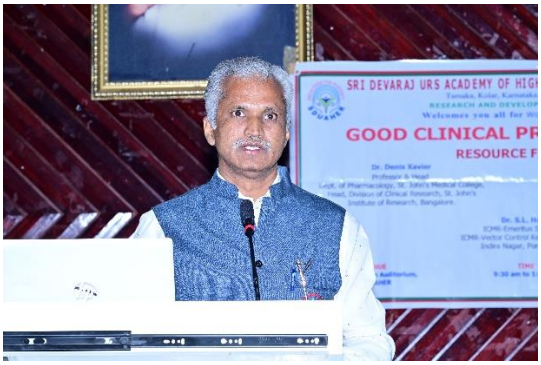




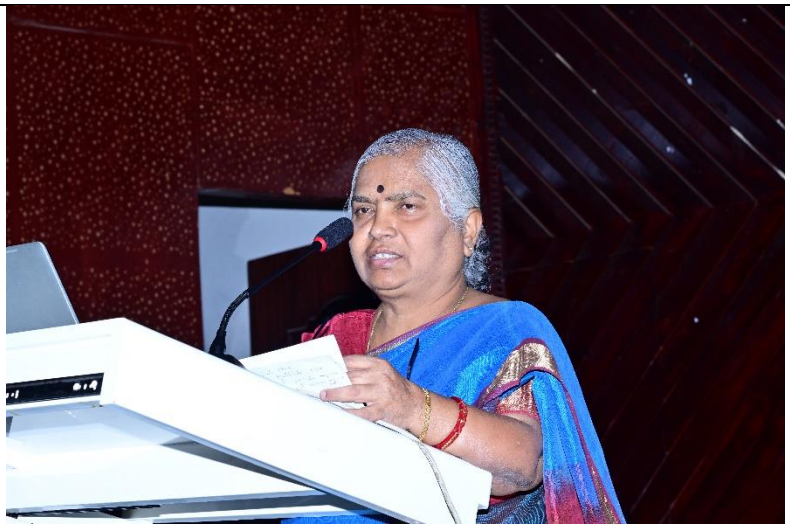


Opening Remarks:

Dr. Muninarayana C, Registrar, SDUAHER highlighted the need and importance of Good Clinical Practice in the context of Clinical trials and advised all the participants to make use of the new knowledge generated from the workshop.



Dr. B Vengamma, Hon'ble Vice Chancellor, SDUAHER provided the insight about the safety and ethical aspects in the conduct of clinical trials and wished all the participants to have a fruitful experience from the talks of the Resource persons and utilize them in clinical practice.

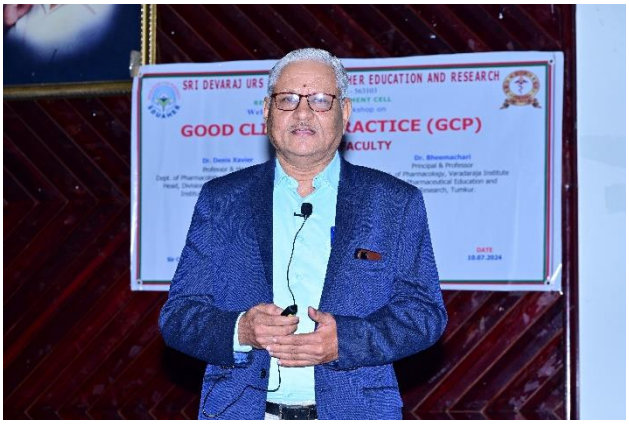


Talk 1

Dr Denis Xavier: Professor and Head of Pharmacology (Ex Vice Dean), Head, Divn. of Clinical Research, St. John's Medical College, Bangalore. Rendered detailed talk on topic titled **Overview of Principles in GCP** and stressed that the principles in GCP collectively ensure that clinical trials are conducted with the highest ethical standards, maintain participant safety, and produce reliable data that can be used to evaluate investigational products and advance medical knowledge. Compliance with GCP principles is crucial for obtaining regulatory approval and ensuring the credibility and acceptability of trial results.

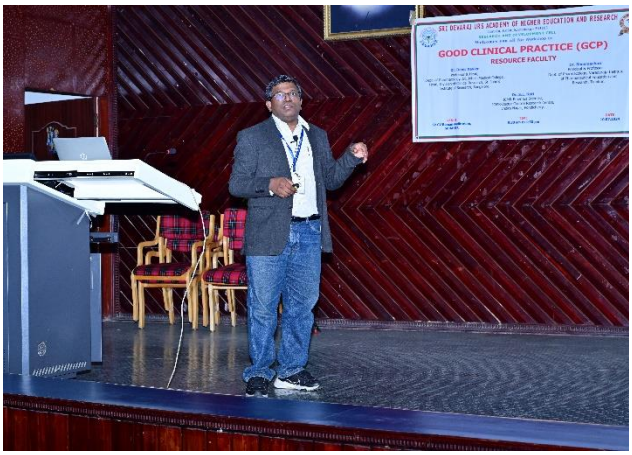
Talk 2

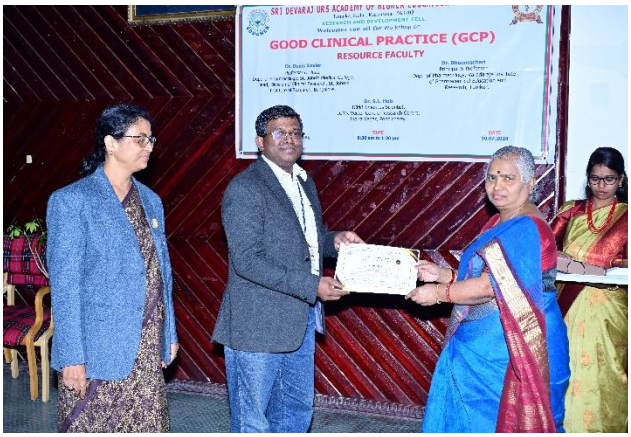
Dr. Bheemachari: Principal & Professor Dept. of Pharmacology Varadaraja Institute of Pharmaceutical Education and Research, Tumkur**.** Rendered detailed talk on topic titled **GCP in Clinical Trial regulations** and concluded that GCP in clinical trial regulations provides a framework for conducting ethical and scientifically sound research while safeguarding participants' rights and safety. Compliance with GCP guidelines is essential for obtaining regulatory approval and ensuring the reliability of clinical trial data used to support new medical treatments and therapies.



Talk 3

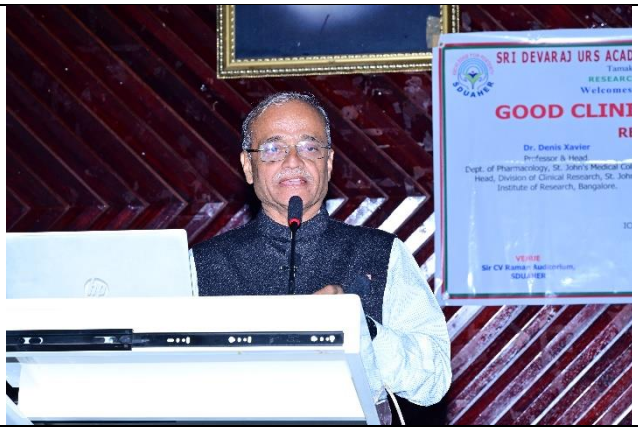
Dr Denis Xavier: Professor and Head of Pharmacology (Ex Vice Dean), Head, Divn. of Clinical Research, St. John's Medical College, Bangalore. Rendered detailed talk on topic titled **Quality assurance and Quality Management in GCP** and emphasized that QA and QM in GCP are essential for ensuring that clinical trials are conducted ethically, adhere to regulatory requirements, and generate reliable data. QA focuses on verifying compliance through audits and reviews, while QM involves strategic planning and continuous improvement to maintain high standards of quality throughout the trial process.

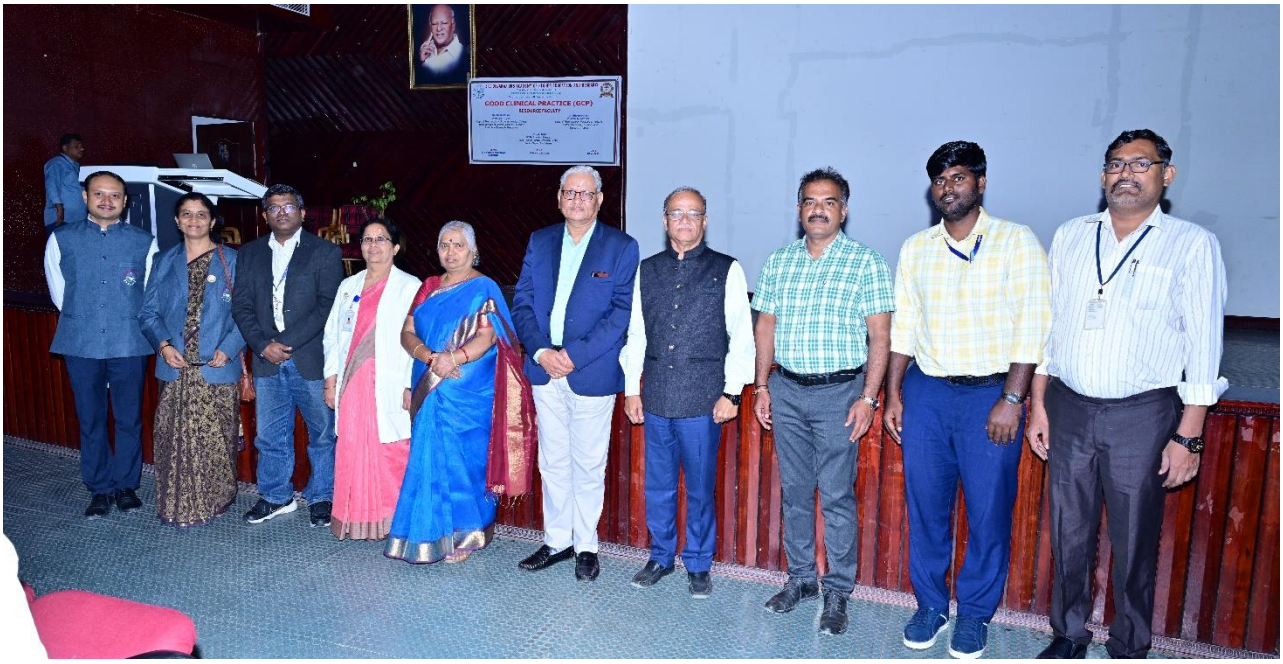




Talk 4

Dr Hoti S L: ICMR-Emeritus Scientist, ICMR-Vector Control Research Centre, Indira Nagar, Puducherry. Rendered detailed talk on topic titled **Ethical and Safety issues in GCP** and emphasized that ethical and safety considerations in GCP are paramount to protect participants' rights and safety, maintain data integrity, and uphold public trust in clinical research. Rigorous adherence to ethical principles and regulatory standards ensures that clinical trials are conducted ethically and with due regard for participant safety throughout the study process.

	 
3.	**Concluding remarks**: The GCP workshop successfully achieved its objective of educating participants on the ethical and regulatory requirements of clinical research. It equipped attendees with essential knowledge and skills to ensure compliance with GCP guidelines, thereby promoting the conduct of ethical and scientifically rigorous clinical trials.
4.	**Participants & delegates:** A total of 140 members participated in the event
5.	**Certificate Distribution**: Distributed to all the participants
6.	**Valedictory Ceremony**: Vote of thanks was proposed by Dr. Sathishbabu P, Core committee member, R & D Cell Followed by Group Photo.



Dignitaries and Resource persons

Organizing Secretary	**Co-Organizing Chairperson**	**Organizing Chairperson**
Dr. Satish Babu P	Dr. Shahsidhar K	Dr. Kalyani R
R&D Core Committee	Deputy Co-Ordinator	Director, R & D Cell
Member, SDUAHER	R&D Cell, SDUAHER	SDUAHER