



# G. Pulla Reddy College of Pharmacy

Mehdipatnam, Hyderabad

Affiliated to Osmania University and Approved by PCI

Accredited By **National Assessment and Accreditation Council (NAAC)**

**Autonomous**



## SKILL DEVELOPMENT COURSE

### HANDS-ON TRAINING ON PHARMACOVIGILANCE

A Three-day Hands-on Training on Pharmacovigilance was organized by G. Pulla Reddy College of Pharmacy from 18<sup>th</sup> to 20<sup>th</sup> December 2025. This certificate training course was conducted with the aim to equip the students with the industrial pharmacovigilance skills and make them job ready. A total of 30 students of Pharm. D 5<sup>th</sup> year completed the training successfully. The course was delivered by industry specialists in Pharmacovigilance.

The following topics were covered during the course:

	Speaker	Topics
Day 1	Mr. Uppu Manesh Kumar Drug Safety Associate Alphacure Life Sciences	Overview of Pharmacovigilance Medical Literature Monitoring <ul style="list-style-type: none"><li>➤ Constructing a precise <b>search string</b></li><li>➤ Systematically <b>pulling the HITS</b> from databases,</li><li>➤ Performing rigorous <b>literature validation</b> to identify relevant safety information</li></ul>
Day 2	Mr. Uppu Manesh Kumar Drug Safety Associate Alphacure Life Sciences	ICSR processing <ul style="list-style-type: none"><li>➤ <b>Book in</b> (receiving adverse event report and registering in safety database),</li><li>➤ <b>Triage</b> (assessing the case to determine priority, seriousness and reporting timelines),</li><li>➤ <b>Data entry</b> of adverse event report in pharmacovigilance safety database,</li><li>➤ <b>Review</b> process including quality review, medical review and follow-up assessment,</li><li>➤ <b>Submission</b> of ICSR to appropriate regulatory authorities</li></ul>
Day 3	Mr. Chanikya Regeti Drug Safety specialist Alphacure Life Sciences	Aggregate reporting <ul style="list-style-type: none"><li>➤ Signal detection</li><li>➤ Periodic adverse drug experience report (PADER),</li><li>➤ Periodic safety update report (PSUR),</li><li>➤ Periodic benefit-risk evaluation report (PBRAR),</li><li>➤ Development safety update report (DSUR)</li></ul>

		➤ Risk evaluation and Mitigation strategy (REMS)
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All the students gave excellent feedback about the course.

The course was coordinated by Mrs. Gouhar Sultana, Assistant Professor, Department of Pharmacy Practice.

