JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

Adverse Drug Reaction Monitoring Centre
&
Regional Training Centre – PvPI, IPC

Department of Clinical Pharmacy
JSS Medical College & Hospital, Mysuru -04

Report on Training Program on Pharmacovigilance

The Regional Training Centre for South Zone- PvPI, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru, conducted a Training Program on Pharmacovigilance for the Students of MSc Medical Pharmacology, JSS Medical College, Mysuru from 2nd June 2025 to 4th June 2025 from 9:30 AM – 12:30 PM at Adverse Drug Reaction Monitoring Centre, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru.

On 2nd June 2025, the program commenced with an insightful session on **"Detection, Reporting, Monitoring & Management of Adverse Drug Reactions"** delivered by Dr. B R Jayadev Kumar, Faculty, JSSCP, Mysuru. This session covered the fundamental principles of pharmacovigilance, including the types and mechanisms of ADRs, the importance of early detection, and the role of healthcare professionals in identifying and reporting adverse drug reaction.

Later, Dr. Rakshith U R, Faculty, JSSCP, Mysuru conducted a comprehensive session on **"Assessment of Adverse Drug Reactions"**, focusing on causality assessment (WHO-UMC and Naranjo scales), severity grading, predictability and preventability of ADRs. This session enabled the students to critically evaluate ADR cases and understand the decision-making process involved in pharmacovigilance.

Dr Jaidev Kumar during the session

Dr Rakshith U R during the session

Further, a '**Hands-on session on documentation of ADRs using the Version 1.4 form'** was facilitated by Ms. Mrithika S, Junior Pharmacovigilance Associate, JSSMCH, Mysuru in order to train the participants in handling and documentation of ADR cases. Later, students practiced through handling and documenting simulated ADR cases, and learned the proper format for data entry, and understood how to extract relevant clinical information for reporting. Emphasis was placed on the completeness and accuracy of data that are crucial for signal detection and regulatory actions.

On 3rd June 2025, Mr. Balaji S, Faculty, JSSCP, Mysuru addressed the participants on **"Medication Incidents: Identification & Prevention"**. This session introduced the students to medication errors, near misses, and potential medication-related hazards, with a focus on high-risk situations, contributing factors, and strategies to minimize errors in clinical settings. Tools like root cause analysis and failure mode effect analysis (FMEA) were briefly discussed.

Further, a 'Ha**nds-on session on documentation of AEFIs using the Version 1.4 form'** was conducted. During this session, students engaged with mock AEFI scenarios to practice filling out the form correctly, emphasizing fields unique to immunization such as vaccine name, batch number, time-to-onset, and immunization schedule.

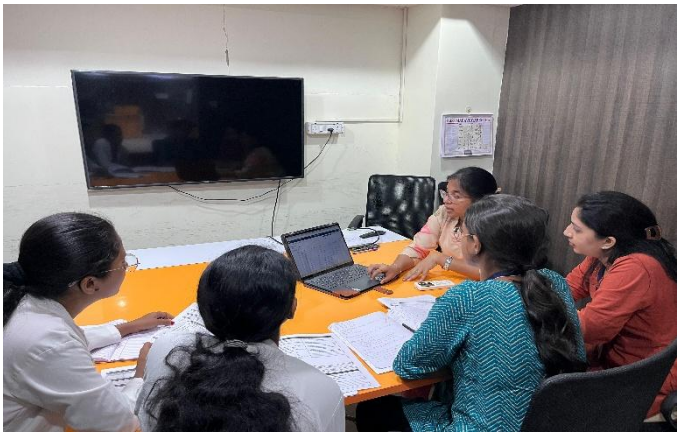
Ms. Mrithika S during the session

Mr. Balaji S during the session

On 4th June 2025, a detailed session on **"Medical Device Adverse Event (MDAE): Detection, Reporting & Documentation"** was conducted by Ms. Mrithika S, focusing on importance of reporting Medical Device related Adverse Events. This session emphasized the identification and reporting of adverse events associated with commonly used medical devices such as IV cannulas, infusion pumps, ventilators, catheters, ECG machines, and monitoring devices. During this session, participants were sensitized to various scenarios including device malfunction, breakage, user error, and compatibility issues that could potentially harm patients. Real-life examples were discussed to highlight the need for prompt detection and accurate documentation.

The importance of proper reporting mechanisms under the Materiovigilance Programme of India (MvPI) was also explained, along with guidelines for filling out MDAE reporting forms to ensure effective surveillance and regulatory action.

The training program concluded with **'Hands-on session on digital ADR and AEFI reporting using the VigiFlow® platform**, and was conducted by Ms. Mrithika S. During this session, participants were trained to create individual case safety report (ICSR), upload them into VigiFlow, and understand how the information integrates into the national pharmacovigilance programme of India (PvPI).



Students attending the session on ADR reporting through vigiflow platform

At the end of the three-day training program, the participants expressed their appreciation for the well-structured and informative sessions. Overall, the training was well-received, and participants conveyed that the program boosted their confidence in detecting, documenting, and reporting ADRs, AEFIs, and MDAEs effectively in clinical practice.
