

**JSS Academy of Higher Education & Research**  
**JSS College of Pharmacy,**  
Sri Shivarathreshwara Nagara, Mysuru

**REPORT ON GUEST LECTURE**

**Speaker:** Dr. Gerald J. Dal Pan, MD, MHS

**Topic:** Overview of Post market Drug Safety

**Date:** 24<sup>th</sup> May 2023

**Students of Program:** 1<sup>st</sup> year and 2<sup>nd</sup> year M. Pharm students and Ph.D. scholars of JSS College of Pharmacy had attended the lecture.

**Mrs. Shilpa Palaksha**, Associate Professor, Department of Pharmacy Practice, introduced the speaker to the students. **Gerald J. Dal Pan** delivered a talk on the topic “Overview of Post market Drug Safety”. The session began with the introduction on “Role of Drug Regulator”.

**Discussion on Overview of Post market Drug Safety**

The Speaker began the session by giving introduction on Drug development and Life cycle Timelines, briefed about the lifecycle of drug safety as an incremental process. He provided insights on how safety could be communicated through product labels and Safety Label Changes for New Molecular Entities 2002-2014.

He detailed about the main sources of Drug safety data and the use of these data sources together provide as complete understanding of the risk of a drug. Case Processing and Review in Spontaneous Reporting Systems (SRS) was detailed in the session.

A few case studies were described to provide the audience a better grasp of the main sources of Drug safety like,

- Azithromycin and the Risk of Cardiovascular death
- Natalizumab

Gerald J. Dal Pan explained about FDA’s Sentinel system and Strategic priorities for innovation.

The session was interactive; **Gerald J. Dal Pan** answered various questions related to the Post-market Drug Safety.

Valuable information about the drug safety was provided by **Gerald J. Dal Pan**. The session was concluded by addressing vote of thanks by **Mrs. Shilpa Palaksha**, Associate Professor, Department of Pharmacy Practice.



**Figure 1: Welcoming the Panel by Mrs. Shilpa Palaksha, Associate Professor, Dept. of Pharmacy Practice.**



**Figure 2: Gerald J. Dal Pan, addressing students about topic "Overview of Postmarket Drug Safety"**



**Figure 3: Interactive session; Question raised by the audience on the Post market safety**



**Figure 4: The Panel was felicitated by Dr. T.M. Pramod Kumar (Principal), Dr. G V Pujar (Vice-Principal)**