

**A Brief Report on Industrial Expert Interaction series 2022 – Lecture 2**

(Enhancing interpersonal and professional skills)

Date: 26.03.2022

***Name of the presenter:***

Mr. Harshil V Patel  
Global RMP Manager,  
Novartis, India ([harshilvpatel@gmail.com](mailto:harshilvpatel@gmail.com))

***Title of the presentation:***

Risk Management Planning in Pharmacovigilance



***Program Organized by:***

Dept. of Pharmacy Practice  
JSS College of Pharmacy, Ooty &

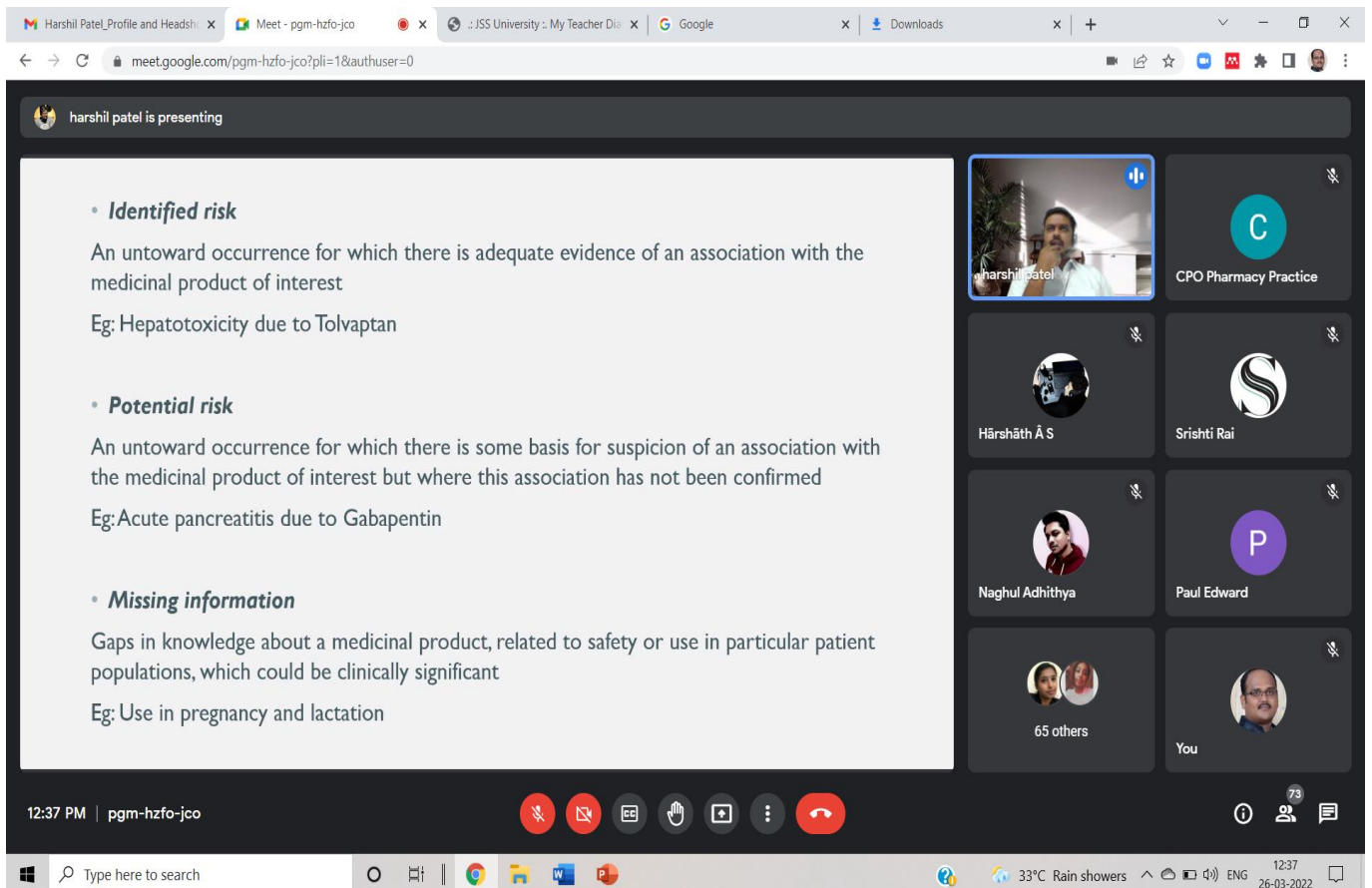
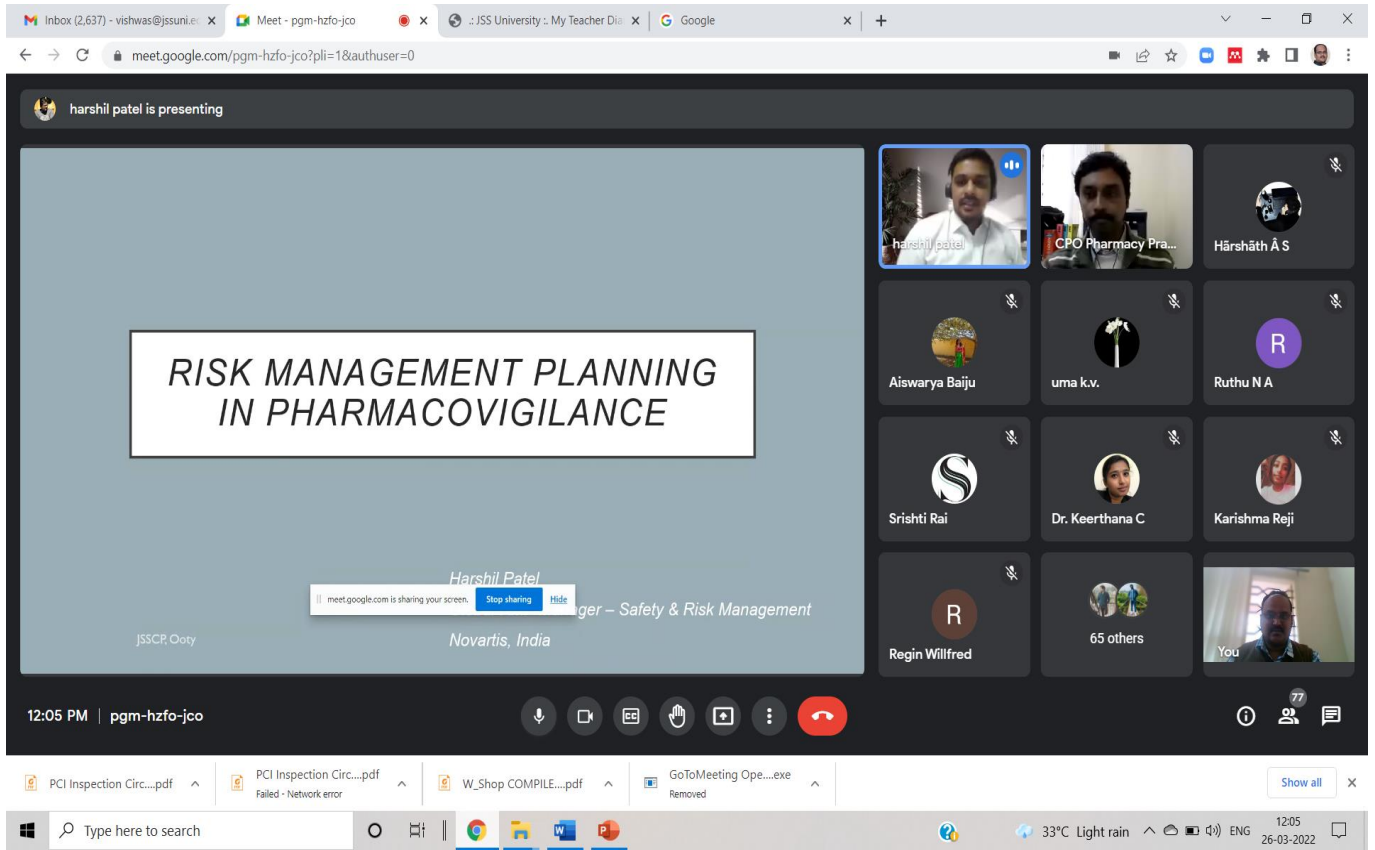
Pharmacy Education Unit  
JSS College of Pharmacy, Ooty

With an objective of enhancing interpersonal and professional skills of the students, Department of Pharmacy Practice in association with Pharmacy Education Unit, JSS College of Pharmacy, Ooty has planned to conduct Industrial Expert Interaction series. Industry expert interactions series provides a platform for budding Pharmacists to be aware of the skills required to enter profession and what Industry expects from the young graduates.

Mr. Harshil V Patel is currently working as a Global RMP Manager with Novartis, Hyderabad. In his current role, he provides strategic support to the medical safety team in the management, coordination, development, reviewing, and tracking of Safety Risk Management Plans. Overall, Harshil has more than 10 years of experience in different aspects of pharmacovigilance domains including case processing, aggregate safety evaluation, risk management plans, and QPPV oversight activities. Mr. Harshil started his career with Sciformix Technologies as a Safety Case Processing Data Analyst. Later, he worked as Faculty of Pharmacy at K.B. Institute of Pharmaceutical Education and Research, Gujarat. He supervised training and research of Pharm D students. Later on, he moved to APCER Life Sciences where he provided expertise and quality consult for Global Aggregate Reports and Risk Management Plans, including pragmatic solutions for tracking and implementation methods. Additionally, he was involved in publication related to additional risk minimization measures dissemination and implementation and represented APCER at various global forums. Mr Harshil is a Clinical Pharmacist by training. He is an alumnus of JSS College of Pharmacy, Mysore and holds M. Pharm degree in Pharmacy Practice.

Mr. Harshil started on the discussion with basics of Pharmacovigilance with the examples of 'Thalidomide, Rofecoxib, Valproate & Fluoroquinolones public hearing. He further explained about the importance of healthcare professionals in risk reduction and risk management. He further elaborated about the purpose of risk management and importance of risk management plan in clinical trials. Mr. Harshil elaborately discussed the various 'risk minimization measures' utilized by Pharma companies. He further discussed the various safety specifications for identified/potential risks. Mr. Harshil further discussed about the 'Factors to be considered for risk minimization tool selection' namely, risk identification, objective of risk minimization and audience for risk minimization intervention. Mr. Harshil explained risk minimization plans implemented for paracetamol and carbamazepine. He further spoke about few regulations related to risk management (DIRECTIVE 2001/83/EC, COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 and FDA Amendments act 2007). He further spoke about risk minimization plans implemented in Asia-pacific region / Latin America and Gulf countries. Finally, he elaborated the Role of pharmacists in risk management in relation to practice perspectives, research perspectives and industrial perspectives.

After the presentation, staff, scholars, PG and Pharm D Students were encouraged to interact through question-and-answer session. Mr Harshil clarified few doubts regarding Pharmacovigilance and risk minimization. The event was coordinated by Dr S Ponnusankar and Mr Vishwas H N, Department of Pharmacy Practice. About 105 participants comprising of students and staff from Department of Pharmacy Practice attended the event.



Few Screen shots of the Industry Expert Interaction Series