

Name of Block	Block-1
Name of Elective	Pharmacovigilance
Location of hospital Lab or research facility	Department of Pharmacology, DMCH
Name of internal preceptor (s)	Dr. Kanchan Gupta
Name of external preceptor (if applicable)	-
Learning objectives of elective	a. Define Pharmacovigilance b. Discuss the importance of Pharmacovigilance c. Describe Pharmacovigilance Programme of India d. Enumerate methods of ADR reporting e. Describe the three scales used for assessment of causality of ADRs f. Describe the scale used for assessment of severity of ADRs g. Describe the scale used for preventability of ADRs h. Fill CDSCO ADR reporting form completely from provided data i. Upload ADR form data into Vigiflow software
Number of students that can be accommodated in this elective	8-10
Pre-requisites for elective	a. Basic knowledge of Adverse Drug Reactions b. Computer literate
Learning resources for students	a. Goodman and Gilman's The Pharmacological Basis of Therapeutics 13th edition b. SOPs issued to AMCs under PvPI c. https://cdsco.gov.in
List of activities of student participation	a. Hospital visit to collect ADR data b. Filling of CDSCO ADR reporting form c. Assessing causality, severity and preventability of ADRs d. Uploading of forms into vigiflow
Portfolio entries required	a. Filled ADR forms along with assessment of causality, severity and preventability b. ADR forms uploaded into Vigiflow software
Log book entry required	At the completion of posting M grade by preceptor
Assessment	a. Formative – attendance, participation in activities b. Summative – presentation in the Dept. and summary report
Other comments	

Adverse Drug Reactions (ADRs) are one of the leading causes of morbidity and represent a substantial economic burden on health-care resources. Pharmacovigilance (PV) involves detection, assessment, understanding, and prevention of adverse effects. The Pharmacovigilance Program of India (PvPI) identifies and responds to drug safety issues. Its activities include receiving and reporting of adverse drug events and taking necessary action. PvPI assists the WHO in developing policy to promote drug safety.

Future health-care professionals need to be competent in handling ADRs in health-care practice and reporting them to the relevant authority. This module will help the students in developing the knowledge, skills and right attitudes related to Pharmacovigilance. It seeks to encourage a culture of reporting ADRs among future doctors. After completion of the module, the student will be able to improve quality of patient care in relation to the use of medicines.

Pharmacovigilance is a challenging yet rewarding field that offers great job opportunities for those who are passionate about making a difference in patient safety.