

PHARMACOVIGILANCE

OPTIONAL COURSE FOR PHARMACY STUDENTS (3rd YEAR)

COURSE OBJECTIVE:

To gain knowledge about pharmacovigilance activities in Romania and the European Union, the types of adverse reactions associated with the administration of medicines, the mechanisms through which these reactions occur, the medicines that can cause such reactions, and the appropriate actions healthcare professionals should take in these situations.

WHAT WILL WE STUDY?

1. Pharmacovigilance: definition, history, and objectives. Pharmacovigilance activities in Romania. The role of the National Agency for Medicines and Medical Devices (ANMDM) in pharmacovigilance activities.
2. The pharmacist's role in pharmacovigilance.
3. Adverse drug reactions: classification, mechanisms of action, and drug interactions.
4. Adverse events. Reporting an adverse reaction. Spontaneous adverse-reaction reporting systems.
5. Dermatological adverse drug reactions.
6. Gastrointestinal adverse drug reactions.
7. Hepatic adverse drug reactions.
8. Cardiovascular adverse drug reactions.
9. Hematological adverse drug reactions.
10. Renal adverse drug reactions.
11. Pharmacovigilance considerations during pregnancy and breastfeeding.
12. Pharmacovigilance considerations in pediatrics.
13. Pharmacovigilance considerations in geriatrics



WHY IS THIS OPTIONAL COURSE USEFUL?

The pharmacovigilance course is an essential component of the education of future pharmacists, playing a major role in monitoring and managing adverse drug reactions. By learning about pharmacovigilance systems in Romania and the European Union, the types of adverse reactions, the mechanisms through which they occur, and the medicines involved, students acquire essential skills for identifying, managing, and reporting adverse reactions. This course develops professional responsibility, critical thinking, and the ability to actively contribute to public safety, in line with European standards and the current requirements of pharmaceutical practice.

CAREERS IN PHARMACOVIGILANCE

1. Pharmacovigilance specialist within pharmaceutical companies or CROs (Contract Research Organizations).
2. Pharmacist working for regulatory authorities, such as the Romanian National Agency for Medicines and Medical Devices (ANMDMR) or the European Medicines Agency (EMA).
3. Drug safety officer within the pharmacovigilance departments of pharmaceutical companies.
4. Clinical pharmacist involved in identifying and managing adverse reactions in hospitals.
5. Health policy or pharmaceutical-regulation consultant.
6. Researcher in the field of medicine safety.