Pharmacovigilance/ Drug Safety theory:

- History and overview of Pharmacovigilance
- Regulatory Authorities country wise
- Pharmacovigilance in India
- Spontaneous reporting
- Active pharmacovigilance
- Cohort Event Monitoring
- Adverse Events and its types
- Drug Safety in clinical trials and post marketed drugs
- Different sources of Adverse Events reporting
- Different types of AE Reporting Forms
- Expedited reporting and its timelines
- Aggregate reporting
- Different departments working on Pharmacovigilance
- Business workflow of Pharmacovigilance
- Minimum criteria for the case
- Causality assessment of the adverse event
- Expectedness assessment of the adverse event
- Seriousness assessment of the adverse event
- MedDRA and WHODD coding
- SAE narrative writing and Templates
- PBRER/PSUR and its submission timelines
- E2A-E2F Guidelines
- PADAR
- Explanation of Safety Signals, Signal Detection at UMC
- Signal publication and communicating signal
- Risk management