

## <Core Curriculum>

Pharmacovigilance Curriculum	
I . Introduction of PV system	
1	Pharmacovigilance system–Definition
2	ICH Guideline – ICH E2B, E2C, E2D
3	Pharmacovigilance Methods – Passive Surveillance vs Active Surveillance
II . Adverse Event(AE) Reporting and collecting	
1	Terms of AE Reporting – MedDRA, WHO–ART
2	Ways to encourage AE reporting
3	Medication error reporting system and feedback
III . Adverse Event(AE) Analysis and Assessment	
1	Causality Assessment of ICSR(Individual Case Safety Reports) – Method, Considerations(with case studies)
2	AE Analysis(Data mining) – Criteria(PRR, ROR etc)
3	AE Reports Review Method
4	AE Assessment(Signal Detection) – Definition, Method(with case studies)
5	Risk and Benefit Assessment – Definition, Quantative and Qualitive assessments
6	Pharmacoepidemiology – Definition, Method, Evidence–based decision making
7	Pharmacovigilance Inspection
IV . Risk Management and Risk Communication	
1	Risk Management system – Definition, Methods
2	Types of Safety Measures – Recall, Revocation of permission, etc.
3	Decision Making Methods
4	Risk Communication Methods
5	How to Effective Risk Communication