

Aggregate Reporting		
Contents (Division of Teaching hours)		
1	Introduction to Aggregate reporting	1 Hour
2	Introduction, Scope, Terminology, Frequency and Timing of PSUR's/PBRERs	1 Hour
3	Comparison of PSUR and PBRER	1 Hour
4	<ul style="list-style-type: none"> GVP Module VII/ICH E2C R2 guidelines Sections of PSUR/PBRERs Distribution of PSURs/PBRERs 	3 Hours
5	PSUR/PBRER Template (including appendices)	2 Hours
6	Signal detection and signal prioritisation	2 Hours
7	Signal and risk evaluation	2 Hours
8	Benefit-risk analysis evaluation	2 Hours
9	PBRER Process (initiation –submission)	1 Hour
10	Preparation of a sample PSUR/PBRER	3 Hours
11	<ul style="list-style-type: none"> Guid on submission & contents of PSUR's in special situations/addendum PSURs Q & A session 	1 Hour
12	Handling literature in aggregate reports (PBRER, DSUR aCOs)	2 Hours
13	Introduction to Addendum to Clinical Overview (aCOs)	1 Hour
14	Sections of aCO(including appendices)	2 Hours
15	ACOBusiness process (preparation –submission)	2 Hours
16	Introduction, scope, terminology, frequency and timing of PADER's	1 Hour
17	Contents of PADER's and distribution of PADER's	2 Hours
18	PADER template	2 Hours
19	Preparation of a sample PADER-	2 Hours
20	Introduction, scope, Terminology of DSURs	1 Hour
21	General Principles behind DSUR& Modular approach of regulatory documents preparation	2 Hours
22	Contents of DSUR	2 Hours
23	DSUR template discussion	3 Hours
24	Evaluation of risks and benefit from DSUR	1 Hour
25	Preparation of a sample DSUR (Commercial & Non-commercial sponsors)	3 Hours
26	Facing an technical interview for aggregate reports	1 Hour
Total duration		46 Hours

Training Fee – Classroom: 30K + GST

Training Fee – Online: 33K + GST

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