Planning an Effective Post Market Surveillance Program for Medical Devices and Combination Products

Day 1	
08.30 - 09.00	Registration and Breakfast
09.00 - 09.10	Welcome by Medicoindustrien
09.10 - 16.00	Round the table – Course program, objectives, and expectations Intro to Post-Market Surveillance (PMS) EU regulatory background - From MDD to MDR EU MDR requirements on Post-Market Surveillance (PMS) PMS as part of QMS PMS plan, PMS report and PSUR Who should be involved? Potential pitfalls in operating PMS system PMS – Other regions (PMS on combination products) Vigilance requirements – MIR, trend reporting & FSCA Feedback, complaints, and incidents Wrap-up & closing remarks
12.30 - 13.30	Lunch
	Coffee breaks are provided both morning and afternoon

Day 2	
08.30 - 09.00	Breakfast
09.00 - 12.00	Vigilance requirements cont. Who should be trained? (Vigilance on combination products) Wrap-up & closing remarks
	Coffee break provided in the morning