Course program

Planning an effective post market surveillance program for medical devices

Location: Medicoindustrien, Agern Allé 13, DK - 2970 Hørsholm	
Approx. Times	**Topics**
08.30 – 09.00	Coffee/light breakfast and registration
09.00 – 09.10	Introduction and objectives
09.10 – 09.30	The regulatory background, EU and US
09.30 – 10.15	New requirements under the MDR
10.15 – 10.35	Coffee
10.35 – 11.15	New requirements under the MDR continued
11.15 – 11.30	The business background
11.30 – 12.00	Who should be involved?
12.00 – 13.00	Lunch
13.00 – 13.30	How to set up a PMS – the industry view
13.30 - 14.00	Introducing the Medicoindustrien PMS guideline
14.00 – 14.30	Defining a post market surveillance strategy
14.30 – 14.45	Training of sales and marketing
14.45 – 15:05	Coffee
15.05 – 15.45	PMS integration into the Quality System
15.45 – 16:15	Set-up of an efficient global PMS/vigilance program
16:15 – 16:30	Potential pitfalls in operating a PMS system
16.30 – 16.45	Questions and Close