



The Medical Devices Introductory Course: Principles of Medical Devices Regulation in Europe

Date: Tuesday 27th - Thursday 29th June 2023

Location: TOPRA Office, 6th Floor, 3 Harbour Exchange, London, E14 9GE

Module: 13 of the TOPRA MSc Medical Devices

Module Leader: Richard Vincins

Day 1: Tuesday 27 June		
10:15	Registration	
10:55	Introduction from TOPRA	TOPRA
11:00	Day 1 Welcome and Introduction	Richard Vincins Principal
12:00	Medical Device Classification & Drug Device Borderline	Richard Vincins Principal
13:00	Lunch Break	
14:00	Medical Device Classification & Drug Device Borderline (continued)	Richard Vincins Principal
15:30	Tea and coffee break	
15:45-18:45	Case Study (Part 1)	

Day 2: Wednesday 28 June		
08:30	Day 1 Re-Cap & Day 2 Intro	
08:45	Conformity Assessment & ISO 13485	Howard Dobbs Howard Dobbs Consulting
10:45	Tea and Coffee break	
11:00	Clinical Evaluation & PMCF	Richard Vincins Principal
12:30	Lunch Break	
13:30	In-Vitro Diagnostics	Steve Lee ABHI
15:00	Tea and Coffee break	
15:15-18:00	Case Study (Part 2)	

Day 3: Thursday 29 June

08:30	Day 2 Re-Cap & Day 3 Intro	
08:45	Post-Market Surveillance, Device Vigilance & FSCA	Richard Vincins Principal
10:15	Tea and Coffee break	
10:30	Case Study	
12:00	Lunch Break	
13:00	Risk Management	Peter Bowness MCRA
14:15	Tea and Coffee break	
14:30	Beyond CE Marking	Richard Vincins Principal
16:00-16:15	Closing remarks	