



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

Date: Wednesday 26th - Friday 28th June 2024

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: Wednesday 26th June		
10:15	Registration	
10:55	Introduction from TOPRA	TOPRA
11:00	Day 1 Welcome and Introduction	Richard Vincins Principal
12:00	Lecture 1 part one: Medical Device Classification & Drug Device Borderline	Richard Vincins Principal
13:00	Lunch Break	
14:00	Lecture 1 part two: 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: Thursday 27th June		
08:30	Day 1 Re-Cap & Day 2 Intro	
08:45	Lecture 2 part one: Conformity Assessment	Howard Dobbs Howard Dobbs Consulting
09:45	Lecture 2 part two: ISO 13485	Howard Dobbs Howard Dobbs Consulting
10:45	Tea and Coffee break	
11:00	Lecture 3: Clinical Evaluation & PMCF	Richard Vincins Principal
12:30	Lunch Break	
13:30	Lecture 4: In-Vitro Diagnostics	Steve Lee ABHI
15:00	Tea and Coffee break	
15:15-18:00	Case Study (Part 2)	

Day 3: Friday 28th June

08:30	Day 2 Re-Cap & Day 3 Intro	
08:45	Lecture 5: 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	Lecture 6: Risk Management	Peter Bowness MCRA
14:15	Tea and Coffee break	
14:30	Lecture 7: Beyond CE Marking	Richard Vincins Principal
16:00-16:15	Closing remarks	