



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

Date: Tuesday 5th - Thursday 7th July 2022

Location: Hunton Park Hotel, Essex Ln, Watford, Kings Langley WD4 8PN

Module: 13 of the TOPRA MSc Medical Devices

Chairperson: Jonathan Hughes, JHRA Ltd

Day 1: Tuesday 5 July 2022		
10:15	Registration	
10:55	Introduction from TOPRA	TOPRA
11:00	Day 1 Welcome and Introduction	Jonathan Hughes JHRA
12:00	Medical Device Classification & Drug Device Borderline	Theresa Jeary BSI
13:00	Lunch Break	
14:00	Medical Device Classification & Drug Device Borderline (continued)	Theresa Jeary BSI
15:30	Tea and coffee break	
15:45-18:45	Case Study (Part 1)	Jonathan Hughes JHRA

Day 2: Wednesday 6 July 2022		
08:30	Day 1 Re-Cap & Day 2 Intro	Jonathan Hughes JHRA
08:45	Conformity Assessment & ISO 13485	Howard Dobbs Howard Dobbs Consulting
10:45	Tea and Coffee break	
11:00	Clinical Evaluation & PMCF	Rachel Hattersley Dykes Devdone
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)	Jonathan Hughes JHRA

Day 3: Thursday 7 July 2022

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