



**The Medical Devices Introductory
Course:**

**Principles of Medical Devices
Regulation in Europe**

Module 13 of the TOPRA MSc Medical Devices

Monday 6th July to Friday 10th July 2020

Chairperson:

Jonathan Hughes, JHRA Ltd

All times are UK local (BST)

Monday 6th July 2020

13:00	Introduction from TOPRA	Sinead Whelan TOPRA
13:10	Day 1 Welcome and Introduction	Jonathan Hughes JHRA Ltd
14:10	Medical Device Classification & Drug Device Borderline	Theresa Jeary SFL Regulatory Affairs
15:30	Break	
15:45	Medical Device Classification & Drug Device Borderline (continued)	Theresa Jeary SFL Regulatory Affairs
16:55	Wrap up	Jonathan Hughes JHRA Ltd
17:15	Close of day	

Tuesday 7th July 2020

13:00	Case Study 1 Introduction	Jonathan Hughes JHRA
13:15	Case Study 1 (break to be taken within case study)	
15:30	Case Study Feedback	
16:00	Case Study 2 – Innovation Preparation	
16:30	Close of Day	

Wednesday 8th July 2020

12:00	Reconnect & Introduction	Jonathan Hughes JHRA Ltd
12:10	Conformity Assessment, Technical Documentation & Standards	Howard Dobbs Howard Dobbs Consulting Ltd
14:10	Break	
14:25	Clinical Evaluation, Clinical Investigation & PMCF	Rachel Hattersley Dykes Devdone
15:40	Break	
15:55	In-Vitro Diagnostics	TBC
17:25	Wrap up	Jonathan Hughes JHRA Ltd
17:40	Close of Day	

Thursday 9th July 2020

13:00	Reconnect & Introduction	Jonathan Hughes JHRA Ltd
13:05	Case Study 2 Introduction	Jonathan Hughes JHRA
13:15	Case Study 2 (break to be taken within case study)	
15:15	Case Study Feedback	
15:45	Risk Management	Peter Bowness BSI
17:30	Wrap up	Jonathan Hughes JHRA Ltd
17:40	Close of Day	

Friday 10th July 2020

12:30	Reconnect & Introduction	Jonathan Hughes JHRA Ltd
12:40	Post Market Surveillance, Device Vigilance & Field Safety Corrective Actions	Steve Dew
14:00	Break	
14:15	Case Study 3 Introduction	Jonathan Hughes JHRA
14:20	Case Study 3	
15:05	Case Study Feedback	
15.35	Break	
15.50	Beyond CE Marking	Jonathan Hughes JHRA Ltd
17:20	Wrap up	Jonathan Hughes JHRA Ltd
17:30	Close of Meeting	