



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

*Module 13 of the TOPRA MSc Medical Devices*

**Wednesday 10<sup>th</sup> July to Friday 12<sup>th</sup> July 2019**

**Hunton Park, Hertfordshire, UK**

Chairperson:

Jonathan Hughes, JHRA Ltd

## Wednesday 10<sup>th</sup> July 2019

10.15-10.55	Registration	
10.55	Introduction from TOPRA	<b>Samantha Alsbury</b> TOPRA
11.00	Day 1 Welcome and Introduction	<b>Jonathan Hughes</b> JHRA
12.00	Medical Device Classification & Drug Device Borderline	<b>Theresa Jeary</b> Teleflex Incorporated
13.00	Lunch	
14.00	Medical Device Classification & Drug Device Borderline (continued)	<b>Theresa Jeary</b> Teleflex Incorporated
15.30	Tea and coffee break	
15.45-18.45	Case Study (Part 1)	<b>Jonathan Hughes</b> JHRA
19.00	Welcome Dinner in restaurant	

## Thursday 11<sup>th</sup> July 2019

08.30	Day 1 Re-Cap & Day 2 Intro	<b>Jonathan Hughes</b> JHRA
08.45	Conformity Assessment & ISO 13485	<b>Anne Jury</b> Anne Jury Associates
10.45	Tea and Coffee break	
11.00	Clinical Evaluation & PMCF	<b>Rachel Hattersley Dykes</b> devdone
12.30	Lunch	
13.30	In-Vitro Diagnostics	<b>Nancy Consterdine</b> IVDeology Ltd
15.00	Tea and Coffee break	
15.15-18.00	Case Study (Part 2)	<b>Jonathan Hughes</b> JHRA
19.00	Dinner in restaurant	

## Friday 12<sup>th</sup> July 2019

08.30	Day 2 Re-Cap & Day 3 Intro	Jonathan Hughes JHRA
08.45	Post-Market Surveillance, Device Vigilance & FSCA	Aaron Cousins Beckman Coulter
10.15	Tea and Coffee break	
10.30	Case Study	Aaron Cousins & Jonathan Hughes
11.45	Risk Management (Part one)	Stephan Buttron
12.30	Lunch	
13.30	Risk Management (Part two)	Stephan Buttron
14.15	Tea and Coffee break	
14.30	Beyond CE Marking	Jonathan Hughes JHRA
16.00-16.15	Closing remarks	Jonathan Hughes JHRA