



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

**Date:** Wednesday 7th - Friday 9th July 2021

**Location:** Online

**Module:** 13 of the TOPRA MSc Medical Devices

**Chairperson:** Jonathan Hughes, JHRA Ltd

<b>Day 1: Wednesday 7 July</b>		
<b>10:15</b>	<b>Registration</b>	
<b>10:55</b>	<b>Introduction from TOPRA</b>	<b>Samantha Cooper</b> TOPRA
<b>11:00</b>	<b>Day 1 Welcome and Introduction</b>	<b>Jonathan Hughes</b> JHRA
<b>12:00</b>	<b>Medical Device Classification &amp; Drug Device Borderline</b>	<b>Theresa Jeary</b> BSI
<b>13:00</b>	<b>Lunch Break</b>	
<b>14:00</b>	<b>Medical Device Classification &amp; Drug Device Borderline (continued)</b>	<b>Theresa Jeary</b> BSI
<b>15:30</b>	<b>Tea and coffee break</b>	
<b>15:45-18:45</b>	<b>Case Study (Part 1)</b>	<b>Jonathan Hughes</b> JHRA

<b>Day 2: Thursday 8 July</b>		
<b>08:30</b>	<b>Day 1 Re-Cap &amp; Day 2 Intro</b>	<b>Jonathan Hughes</b> JHRA
<b>08:45</b>	<b>Conformity Assessment &amp; ISO 13485</b>	<b>Howard Dobbs</b> Howard Dobbs Consulting
<b>10:45</b>	<b>Tea and Coffee break</b>	
<b>11:00</b>	<b>Clinical Evaluation &amp; PMCF</b>	<b>Rachel Hattersley Dykes</b> Devdone
<b>12:30</b>	<b>Lunch Break</b>	
<b>13:30</b>	<b>In-Vitro Diagnostics</b>	<b>Sue Spencer</b> QServe
<b>15:00</b>	<b>Tea and Coffee break</b>	
<b>15:15-18:00</b>	<b>Case Study (Part 2)</b>	<b>Jonathan Hughes</b> JHRA

<b>Day 3: Friday 9 July</b>		
<b>08:30</b>	<b>Day 2 Re-Cap &amp; Day 3 Intro</b>	<b>Jonathan Hughes</b> JHRA
<b>08:45</b>	<b>Post-Market Surveillance, Device Vigilance &amp; FSCA</b>	<b>Richard Vincins</b> TCFGRC
<b>10:15</b>	<b>Tea and Coffee break</b>	
<b>10:30</b>	<b>Case Study</b>	<b>Jonathan Hughes</b>
<b>12:00</b>	<b>Lunch Break</b>	
<b>13:00</b>	<b>Risk Management</b>	<b>Richard Vincins</b> TCFGRC
<b>14:15</b>	<b>Tea and Coffee break</b>	
<b>14:30</b>	<b>Beyond CE Marking</b>	<b>Jonathan Hughes</b> JHRA
<b>16:00-16:15</b>	<b>Closing remarks</b>	<b>Jonathan Hughes</b> JHRA