

## Module 18: Drug Device Combinations and other Technology

Date: 6 – 8 December 2023



**LOCATION:** TOPRA OFFICE, LONDON, UK / ONLINE

**Module Leader(s):** Jason Collins and Helen Erwood

### Day 1: Wednesday 6<sup>th</sup> December 2023

Time (GMT)	Activity	Speaker
<b>08.45</b>	Registration	
<b>09.00 – 09.30</b>	Welcome & Introduction to the Module Overview of the regulatory environment for combination products EU MDR, IVDR and US	Jason Collins and Helen Erwood
<b>09.30 – 10.15</b>	Lecture 1: Drug Device Combinations including Ancillary Medicinal Products	Helen Erwood
<b>10.15 – 10.45</b>	<b>Morning break</b>	
<b>10.45 – 11.45</b>	Case Study 1: Classification of DDC's Integral v non-Integral Medicine or Device Pathway	Jason Collins and Helen Erwood
<b>11.45 – 12.45</b>	Lecture 2: IVDR and Companion Diagnostics	Volker Franzen Maranna Sweeney, Qiagen
<b>12.45 – 13.45</b>	<b>Lunch</b>	
<b>13.45 – 14.45</b>	Lecture 3: Borderline Products	Sarah Tang, MHRA
<b>14.45 – 15.00</b>	<b>Afternoon break</b>	
<b>15.00 – 15.45</b>	Lecture 4: Overview of the medicines pathway	Jason Collins
<b>15.45 – 16.30</b>	Case Study 2: Borderlines/Manual of Decisions/Algorithms	Jason Collins and Helen Erwood

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### Day 2: Thursday 7<sup>th</sup> December 2023

Time	Activity	Speaker
09.00 – 09.30	Introduction and review of case study 2	Chairperson Helen Erwood
09.30 – 10.15	Lecture 5: Software as a medical device: A different development approach	David Horton, GSK
10.15 – 10.30	<b>Morning break</b>	
10.30 – 11.15	Lecture 6: Innovative Manufacturing – Rapid Prototyping – the Challenges of Designing and Testing prototypes	Sukie Whitehall, Oval Medical Technologies
11.15 – 12.00	Lecture 7: Devices and ATMPs – Examples and Challenges	Shaun Stapleton, Reneuron
12.00 – 13.00	<b>Lunch</b>	
13.00 – 13.45	Lecture 8: Human Factors for Drug Device Combination Products	Greg Thay
13.45 – 14.30	Case Study 3: Considerations when planning your registration activities	Jason Collins and Helen Erwood
14.30 – 14.45	<b>Afternoon break</b>	
14.45 – 15.30	Lecture 9: Biological Assessments	Stuart Freeman, Farino Consulting

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### Day 3: Friday 8<sup>th</sup> December 2023

Time	Activity	Speaker
<b>09.00 – 09.15</b>	Introduction to day 3	
<b>09.15 – 10.00</b>	Lecture 10: Clinical Evidence	Richard Holborow BSi
<b>10.00 – 10.15</b>	<b>Morning break</b>	
<b>10.15 – 11.00</b>	Case Study 4: Evidence base for different products	Jason Collins / Helen Erwood
<b>11.00 – 11.45</b>	Lecture 11: Notified Body Role and Expectations for DDCs	Theresa Jeary BSi
<b>11.45 – 12.45</b>	<b>Lunch</b>	
<b>12.45 – 13.30</b>	Lecture 12: Regulatory Considerations and Experiences when working with Multi-faceted Products	Jason Collins and Helen Erwood
<b>13.30 – 14.15</b>	Lecture 13: And now for something completely different: The impact of Brexit	Jason Collins and Helen Erwood
<b>14.15 – 14.30</b>	<b>Afternoon break</b>	
<b>14.30 – 16.15</b>	Case study information and recap	Helen Erwood