Module 18: Drug Device Combinations and Other Technology
Date: 03rd -05th March 2026

Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN
Module Leaders: Natasha Bankowski and Phil Warner
Day 1: 3rd March 2026

Time	Activity	Speaker
09:00 – 09:45	**Registration** **Welcome & Introduction to the Module**	**Natasha Bankowski** **Phil Warner**
09:45 – 10:45	**Lecture 1: Drug Device Combinations including Ancillary Medicinal Products** • What is a Drug Device Combination? • Devices incorporating Ancillary Medicinal Product • Who regulates DDCs and Devices incorporating Ancillary Medicinal Product? • Legislation governing DDCs in the EU • What is Article 117 of the EU MDR? • Regulatory process for assessment of a DDC	**TBC**
10:45 – 11:15	**Refreshment Break**	
11:15 – 12:15	**Case Study 1:** Classification of DDCs Integral v non-Integral Medicine or Device Pathway	**Natasha Bankowski** **Phil Warner**
12:15 – 13:15	**Lecture 2: Companion Diagnostics and the IVDR** • What is an IVD? • What is a companion diagnostic (CDx)? • CDx and the IVDR • Understand the personalised medicine context for CDx • Understand the implications of the IVDR for developers of both personalised medicines and CDx	**TBC**
13:15 – 14:00	**Lunch**	
14:00 – 15:00	**Lecture 3: Borderline products and classification** • What is a borderline product? • Is the product a medicinal product, medical device, IVD, cosmetic or other? • Borderline products in the context of DDCs • How to get a decision on a borderline product?	**TBC**
15:00 – 16:00	**Case Study 2:** Borderline products Determine what classification options there might be for the products (medicines, medical devices or cosmetics)	**Natasha Bankowski** **Phil Warner**
16:00 – 16:15	**Refreshment Break**	
16:00 – 17:30	**Lecture 4: Global Regulations for DDCs, including UK and USA** • Regulation of DDCs in the UK • Regulation of DDCs in the USA • Global Combination product regulations • Challenges in seeking approval for DDCs in multiple markets	**Natasha Bankowski**

Module 18: Drug Device Combinations and Other Technology
Date: 03rd -05th March 2026

Day 2: 4th March 2026

Time	Activity	Speaker
09:00 – 09.30	**Introduction to Day 2 and review of Day 1**	**Natasha Binkowski** **Phil Warner**
09:30 – 10:30	**Lecture 5: Design and Development of DDCs** • Strategy and Planning • Conceptualisation and Design Inputs • Prototyping and Engineering • Design Verification and Validation • Manufacturing and Process Validation	**TBC**
10:30 – 10:45	**Refreshment Break**	
10:45 - 11:45	**Lecture 6: DDC products with software-integrated therapies** • Software as a critical component for delivery, monitoring, or analysis • Software as a Medical Device (SaMD) • Platform approach • Lifecycle management • Regulatory complexity • Data security and privacy	**Lisa Donlon** DLSC
11:45 – 12:45	**Lecture 7: Clinical Strategy for a DDC** • Is a clinical trial or a Clinical Investigation/performance study needed, or both? • Clinical Trial submission and approval process • COMBINE project • Clinical evidence required for a DDC	**TBC**
12:45 – 13:30	**Lunch**	
13:30 – 14:30	**Lecture 8: Human Factors for DDCs** • What is Usability? • What is Human Factors? • What is the Human Factors and Usability Engineering process • Evaluating drug delivery devices in Human Factors and Usability Tests	**TBC**
14:30 - 15:30	**Case Study 3: TBC**	**Natasha Binkowski** **Phil Warner**
15:30 – 15:45	**Refreshment Break**	
15:45 – 16:45	**Lecture 9: Technical Documentation for a DDC** • Understanding the CTD – Common Technical Document • Examine all five modules of the CTD M1-M5 • Understanding the EU Technical file • The General Safety and Performance Requirements (GSPRs) • Where to place combined data for a DDC in a CTD	**TBC**
16:45 – 17:45	**Lecture 10: Non-clinical Data and Biocompatibility for a DDC** • Biocompatibility Studies (ISO 10993) • Drug-Device Interaction Studies • Device Performance and Engineering Data • Toxicological Assessment	**TBC**

Module 18: Drug Device Combinations and Other Technology
Date: 03rd -05th March 2026

Day 3: 5th March 2026

Time	Activity	Speaker
09:00 – 09:30	**Introduction to Day 3 and Review of Day 2**	**Natasha Bankowski Phil Warner**
09:30 – 10:30	**Lecture 11: Role of the Notified Body in the DDC assessment process** • Role of the Notified Body • Assessment of devices with an Ancillary Medicinal Product • Role of the Notified Body in assessment of single integral DDCs and Article 117 • Content of the Notified Body Opinion submission	**TBC**
10:30 – 10:45	**Refreshment Break**	
10:45 - 12:30	**Case Study 4: TBC**	**Natasha Bankowski Phil Warner**
12:30 – 13:30	**Lunch**	
13:30 – 14:30	**Lecture 12: Lifecycle Management for DDCs** • What is a variation? • What is a significant change? • How to handle a post-approval change? • Is the original NBOp impacted by a post-approval change?	**TBC**
14:30 – 14:45	**Refreshment Break**	
14:45 – 15:45	**Lecture 13: Post market and Vigilance requirements for a DDC** • What is Pharmacovigilance? • What is device vigilance? • Reporting requirements for a DDC • Post-market requirements for a DDC	**TBC**
15:45	**Close**	