

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 <ul style="list-style-type: none">• 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	Natasha Bankowski
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 <ul style="list-style-type: none">• 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	Ben Jacoby Cambridge RA Ltd
13:15 – 14:00	Lunch	
14:00 – 15:00	Lecture 3: Borderline products and classification <ul style="list-style-type: none">• 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?	Jonathan Sutch BSI
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	
16:15 – 17:30	Lecture 4: Clinical Strategy for a DDC <ul style="list-style-type: none">• 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	Amber McNair IQVIA

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Day 2: 4th March 2026

Time	Activity	Speaker
09:00 – 09:30	Introduction to Day 2 and review of Day 1	Natasha Bankowski Phil Warner
09:30 – 10:30	Lecture 5: Design and Development of DDCs <ul style="list-style-type: none">• Strategy and Planning• Conceptualisation and Design Inputs• Prototyping and Engineering• Design Verification and Validation• Manufacturing and Process Validation	Abha Raveau – Violette Combination Products and Medical Device Ltd
10:30 – 10:45	Refreshment Break	
10:45 – 11:45	Lecture 6: DDC products with software-integrated therapies <ul style="list-style-type: none">• 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 Donlon Life Science Consulting Ltd
11:45 – 12:45	Lecture 7: Human Factors for DDCs <ul style="list-style-type: none">• 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	Grey Thay Thay Medical
12:45 – 13:30	Lunch	
13:30 – 14:30	Lecture 8: Technical Documentation for a DDC <ul style="list-style-type: none">• 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	Louise Place GSK
14:30 – 15:30	Case Study 3: TBC	Natasha Bankowski Phil Warner Louise Place
15:30 – 15:45	Refreshment Break	
15:45 – 16:45	Lecture 9: Lifecycle Management for DDCs <ul style="list-style-type: none">• 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?	Louise Place GSK
16:45 – 17:45	Lecture 10: Non-clinical Data and Biocompatibility for a DDC <ul style="list-style-type: none">• Biocompatibility Studies (ISO 10993)• Drug-Device Interaction Studies	Elisabet Jamez Pieter Van Wouwe Nelson Labs

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- Device Performance and Engineering Data
- Toxicological Assessment

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 <ul style="list-style-type: none">• 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	Theresa Jeary BSI
10:30 – 10:45	Refreshment Break	
10:45 - 12:30	Case Study 4:	Natasha Bankowski Phil Warner Louise Place
12:30 – 13:30	Lunch	
13:30 – 14:30	Lecture 12: Global Regulations for DDCs, including UK and USA <ul style="list-style-type: none">• 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	Daniel Hill MHRA Natasha Bankowski
14:30 – 14:45	Refreshment Break	
14:45 – 15:45	Lecture 13: Post-market and Vigilance requirements for a DDC <ul style="list-style-type: none">• What is Pharmacovigilance?• What is device vigilance?• Reporting requirements for a DDC• Post-market requirements for a DDC	Eleri Abreo Arnold and Porter
15:45	Close	