

Module: 13 Principles of Medical Device Regulatory Affairs

Date: 02/06/2026-04/06/2026



Location: RIU Plaza The Gresham Dublin, 23 O'Connell Street Upper, D01 C3W7, Dublin

Module Leader: Richard A. Vincins

Day 1: 2nd June 2026

Time	Activity	Speaker
10:15 – 11:00	Registration Welcome & Introduction to the Module	Richard Vincins MD Compliance
11:00 – 12:00	Lecture 1: Introduction, Basics of Requirements, Economic Operators, Scope of Regulations in Europe (European Union and the United Kingdom)	Richard Vincins MD Compliance
12:00 – 13:00	Lecture 2 Part One: Medical Device Classification, Rules, Borderline Products, Combination Products	Richard Vincins MD Compliance
13:00 – 14:00	Lunch	
14:00 – 15:30	Lecture 2 Part Two: Medical Device Classification, Rules, Borderline Products, Combination Products (continued)	Richard Vincins MD Compliance
15:30 – 15:45	Refreshment Break	
15:45 – 18:45	Case Study 1	Richard Vincins MD Compliance

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Day 2: 3rd June 2026

Time	Activity	Speaker
08:30 – 08:45	Introduction to Day 2 and review of Day 1	Richard Vincins MD Compliance
08:45 – 09:45	Lecture 3: Conformity Assessment Routes for CE Marking and UKCA; High-Risk Devices	Rebecca Hird TÜV SÜD
09:45 – 10:45	Lecture 4: Quality Management System Requirements, Roles and Responsibilities, ISO 13485 Conformance	Rebecca Swindell MD Compliance
10:45 – 11:00	Refreshment Break	
11:00 – 12:30	Lecture 5: Technical Documentation, Structure and Content, Submission Process, General Safety and Performance Requirements (GSPR)	Richard Vincins MD Compliance
12:30 – 13:30	Lunch	
13:30 – 15:00	Lecture 6: Clinical Evaluation Process, Clinical Evidence, Clinical Investigations, Post Market Clinical Follow-Up (PMCF)	Rachel Hattersley-Dykes Devdone
15:00 – 15:15	Refreshment Break	
15:15 – 18:00	Case Study 2	Richard Vincins MD Compliance

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Day 3: 4th June 2026

Time	Activity	Speaker
08:30 – 08:45	Introduction to Day 3 and Review of Day 2	Richard Vincins MD Compliance
08:45 – 10:15	Lecture 7: Post-Market Surveillance, Vigilance Processes, Serious Incident Reporting (EU and UK), Trending	Rebecca Swindell Richard Vincins MD Compliance
10:15 – 10:30	Refreshment Break	
10:30 – 12:00	Case Study 3	Richard Vincins MD Compliance
12:00 – 13:00	Lunch	
13:00 – 14:15	Lecture 8: UDI, EUDAMED, UK Registration Conformity Assessment Audits	Richard Vincins MD Compliance
14:15 – 14:30	Refreshment Break	
14:30 – 16:00	Lecture 9: Global Medical Device Requirements and Comparison	Richard Vincins MD Compliance
16:00 – 16:15	Close	