



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

Date: Monday 16th - Wednesday 18th June 2025

Location: TOPRA Office, 3rd Floor, 5-6 Greenwich View Place, City Reach, London E14 9NN

Module: 13 of the TOPRA MSc Medical Devices

Module Leader: Richard A. VINCINS

Day 1: Monday 16 th June		
10:15	Registration	
10:55	Introduction from TOPRA	TOPRA
11:00	Day 1 Welcome Lecture 1: Introduction, Basics of Requirements, Economic Operators, Scope of Regulations in Europe (European Union and the United Kingdom)	Richard Vincins NAMSA
12:00	Lecture 2 Part One: Medical Device Classification, Rules, Borderline Products, Combination Products	Richard Vincins NAMSA
13:00	Lunch Break	
14:00	Lecture 2 Part Two: Medical Device Classification, Rules, Borderline Products, Combination Products (continued)	Richard Vincins NAMSA
15:30	Tea and coffee break	
15:45-18:45	Case Study One [1]	

Day 2: Tuesday 17 th June		
08:30	Day 1 Re-Cap & Day 2 Intro	
08:45	Lecture 3: Conformity Assessment Routes for CE Marking and UKCA; High-Risk Devices	
09:45	Lecture 4: Quality Management System Requirements, Roles and Responsibilities, ISO 13485 Conformance	
10:45	Tea and Coffee break	
11:00	Lecture 5: Technical Documentation, Structure and Content, Submission Process, General Safety and Performance Requirements (GSPR)	Rachel Hird TUV SUD
12:30	Lunch Break	
13:30	Lecture 6: Clinical Evaluation Process, Clinical Evidence, Clinical Investigations, Post Market Clinical Follow-Up (PMCF)	Rachel Hattersley-Dykes Devdone
15:00	Tea and Coffee break	

15:15-18:00	Case Study Two [2]	
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Day 3: Wednesday 18th June		
08:30	Day 2 Re-Cap & Day 3 Intro	
08:45	Lecture 7: Post-Market Surveillance, Vigilance Processes, Serious Incident Reporting (EU and UK), Trending	
10:15	Tea and Coffee break	
10:30	Case Study Three [3]	
12:00	Lunch Break	
13:00	Lecture 8: UDI, EUDAMED, UK Registration Conformity Assessment Audits	
14:15	Tea and Coffee break	
14:30	Lecture 9: Global Medical Device Requirements and Comparison	Richard Vincins NAMSA
16:00-16:15	Closing remarks	