IVDD to IVDR Transition

Day 1

Time	Topic
09.00 – 16.00	Benefits to you, welcome and introductions
	Boundaries: Conflict of interest and expertise
	Course aim, learning objectives and course structure
	Background to EU and CE marking
	A new regulation
	Transitioning to the new regulation • Responsibilities
	End of day 1

Day 2

Time	Topic
09.00 – 16.00	Welcome to day 2
	Continue with:
	Transitioning to the new regulation • Scope and risk based classification • Conformity assessment • Clinical expectations • Technical documentation • General safety and performance requirements • Post-market activities • Managing the transition
	Summary
	Course review and final questions