

Essentials of European Medical Device Regulatory Affairs



Programme

Please note all times are in BST (CEST -1 hour)

Time	Presentation	Speaker
09:00	Introduction from TOPRA	Raluca Radu TOPRA
09:05	Introduction	Theresa Jeary BSI Group
09:15	Scope and definitions	Angela Stokes Sharp Regulatory Consulting Limited
10:05	Making available on the market and putting into service of device, obligations of economic operators, reprocessing, CE marking and free movement	Theresa Jeary
10:40	Break	
10:55	Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European data base on medical devices.	Theresa Jeary
11:10	Notified bodies	Theresa Jeary
11:35	Classification and conformity assessment	Angela Stokes
12:30	Lunch Break	
13:15	Conformity Assessment – Annex IX – XI	Theresa Jeary
13:45	Clinical evaluation and clinical investigation	Angela Stokes
14:30	Break	
14:35	Post-market surveillance vigilance and market surveillance	Theresa Jeary
15:05	Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers	Theresa Jeary
15:10	Confidentiality, data protection, funding and penalties	Angela Stokes
15:15	Final provisions	Angela Stokes
15:20	Annex 1 and labelling	Angela Stokes
16:00	Close	