Essentials of European Medical Device Regulatory Affairs

Programme 12 June 2024

TOPRA office, 6th Floor, Harbour Exchange, London E14 9GE

Please note all times are in BST

Time	Presentation	Speaker
09:00	Introduction from TOPRA	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	**Angela Stokes**
12:15	Lunch Break	
13:00	Conformity Assessment – Annex IX – XI	**Theresa Jeary**
13:45	Clinical evaluation and clinical investigation	**Angela Stokes**
14:15	Break	
14:30	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**
15:15	Confidentiality, data protection, funding and penalties	**Angela Stokes**
15:20	Final provisions	**Theresa Jeary**
15:30	Annex 1 and labelling	**Angela Stokes**
15.45	Technical documentation	**Theresa Jeary**
16:00	Close	