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	**Samantha Cooper** TOPRA
09:05	Introduction	**Theresa Jeary** Regulatory & Scientific Affairs Limited
09:15	Scope and definitions	**Janis Bayley** Eli Lilly & Company Ltd
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	
11:10	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**
11:25	Notified bodies	**Theresa Jeary**
11:50	Classification and conformity assessment	**Janis Bayley**
12:20	Break	
12:50	Clinical evaluation and clinical investigation	**Janis Bayley**
13:30	Post-market surveillance vigilance and market surveillance	**Theresa Jeary**
14:15	Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers	**Theresa Jeary**
14:20	Break	
14:30	Confidentiality, data protection, funding and penalties	**Janis Bayley**
14:35	Final provisions	**Janis Bayley**
14:40	Annex 1 and labelling	**Janis Bayley**
15:20	Conformity assessment	**Theresa Jeary**
16:00	Close	