Essentials of European Medical Device Regulatory Affairs

23 June 2020

Programme

Presenters:

Janis Bayley, Eli Lilly & Company and Theresa Jeary, Regulatory & Scientific Affairs Ltd

All times are UK local (BST)

Time	**Presentation**	
10am	Introduction from TOPRA	Cristina Dragan, TOPRA
10.05am	Introduction	Theresa Jeary
10.15am	Scope and definitions	Janis Bayley
11am	Making available on the market and putting into service of device, obligations of economic operators, reprocessing, CE marking and free movement	Theresa Jeary
11.30am	Break	
12pm	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
12.15pm	Notified bodies	Theresa Jeary
12.35pm	Classification and conformity assessment	Janis Bayley
1pm	Break	
1.30pm	Clinical evaluation and clinical investigation	Janis Bayley
2.10pm	Postmarket surveillance vigilance and market surveillance	Theresa Jeary
2.45pm	Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers	Theresa Jeary
2.50pm	Break	
3.10pm	Confidentiality, data protection, funding and penalties	Janis Bayley
3.15pm	Final provisions	Janis Bayley
3.20pm	Annex 1 and labelling	Janis Bayley
4pm	Conformity assessment	Theresa Jeary
5pm	Close	