Location: TOPRA Office, 6th Floor, 3 Harbour Exchange, London E14 9GE and online

Module Leader: Theresa Jeary

Date: Monday 5th September 2022

Time	Activity	Speaker
13:00	**Registration and Welcome and Introduction**	Kay Platt
13.30 – 15.00	Lecture 1: Where are we with the MDR? PMS European Requirements New Legislation Vs Current	Stephan Buttron Buttron Consulting
15.00 – 15.30	Refreshment Break	
15:30 – 17:00	Lecture 2: Unique Device Identification & Traceability in healthcare • UDI • Eudamed and Databases • Traceability Module requirements and availability	Jenny Young-Gough JYG Consulting

Date: Tuesday 6th September 2022

Time	Activity	Speaker
09:00 – 10:00	Lecture 3: The Role and Responsibility of Notified Bodies in Vigilance and Post Market Surveillance	Theresa Jeary BSI
10.00 – 10.30	Refreshment Break	
10.30 – 11.30	Lecture 4: Risk Management/Risk Assessment	David Roe Novartis
11.30 – 12.30	Lunch	
12.30 – 13.30	Case Study	
13.30 – 14.30	Lecture 5: Post Market Surveillance and Corrective and Preventive Actions:	James Pink NSF
14.30 - 15.00	Refreshment Break	
15.00 - 16.00	Lecture 6: Periodic Safety Update Report • SSCP Guidance 2.12 1 rev 8	Adrian Keene Namsa
16.00 - 17.30	Lecture 7: Post Market Clinical Follow Up • Plan • Implementation Overview • PMCF studies PMCF evaluation report	Adrian Keene Namsa

Date: Wednesday 7th September 2022

Time	Activity	Speaker
09.30 – 10.30	Lecture 8: Vigilance Reporting – an Agency perspective • Common issues and pitfalls to avoid	Tony Sant MHRA
10.30 – 11.00	Refreshment Break	
11.00 – 12.30	Lecture 9: Post Market Surveillance - Legal Considerations • Criminal and administrative liabilities • Considerations for listed companies Public Relations	Grant Castle Covington & Burling LLP
12:30 – 13:30	Lunch	
13.30 – 15.00	Lecture 10: Field Safety Corrective Actions - Legal Considerations • Field safety corrective actions • Safeguard measures Product liability	Grant Castle Covington & Burling LLP
15.00 – 15.30	Close of Module	