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

Module Leader: Adrian Keene & Paul Risborough

Date: Wednesday 23rd October 2024

Time	Activity	Speaker
13:00	**Registration and Welcome and Introduction**	
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: Thursday 24th October 2024

Time	Activity	Speaker
09:00 – 10:00	Lecture 3: Post-market surveillance requirements under the MDR (EU) 2017/745	Paul Risborough NAMSA
10.00 – 10.30	Refreshment Break	
10.30 – 11.30	Lecture 4: The role and responsibilities of Notified Bodies in Vigilance and Post-market Surveillance	Monisha Phillips TUV SUD
11.30 – 12.30	Lunch	
12.30 – 13.30	Lecture 5: Post-market surveillance, risk assessment and corrective/preventative action	Paul Risborough NAMSA
13.30 – 14.30	Case Study: Assessing complaints	David Mandley NAMSA
14.30 - 15.00	Refreshment Break	
15.00 - 16.00	Lecture 6: Periodic Safety Update Report (PSUR)	David Mandley NAMSA
16.00 - 17.00	Lecture 7: Post-market Clinical Follow-up (PMCF)	Adrian Keene NAMSA

Date: Friday 25th October 2024

Time	Activity	Speaker
09.30 – 10.30	Lecture 8: Vigilance Reporting – an Agency perspective • Common issues and pitfalls to avoid • Reporting of serious incidents and field safety corrective actions • Transparency schemes • Borderline issues on Medical Devices	Inga Bellahn 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	