

Post Market Surveillance and Vigilance for Medical Devices

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

Module Leader: TBC

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 Confirmed remote
15.00 – 15.30	Refreshment Break	
15:30 – 17:00	Lecture 2: Unique Device Identification & Traceability in healthcare <ul style="list-style-type: none">• UDI• Eudamed and Databases• Traceability Module requirements and availability	Jenny Young-Gough JYG Consulting Confirmed

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Date: Thursday 24th October 2024

Time	Activity	Speaker
09:00 – 10:00	Lecture 3: The Role and Responsibility of Notified Bodies in Vigilance and Post Market Surveillance	TBC
10.00 – 10.30	Refreshment Break	
10.30 – 11.30	Lecture 4: Risk Management/Risk Assessment	TBC
11.30 – 12.30	Lunch	
12.30 – 13.30	Case Study	John Deavin
13.30 – 14.30	Lecture 5: Post Market Surveillance and Corrective and Preventive Actions:	TBC
14.30 - 15.00	Refreshment Break	
15.00 - 16.00	Lecture 6: Periodic Safety Update Report <ul style="list-style-type: none">• SSCP Guidance 2.12 1 rev 8	Adrian Keene Namsa Confirmed remote
16.00 - 17.30	Lecture 7: Post Market Clinical Follow Up <ul style="list-style-type: none">• Plan• Implementation Overview• PMCF studies PMCF evaluation report	Adrian Keene Namsa Confirmed remote

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Date: Friday 25th October 2024

Time	Activity	Speaker
09.30 – 10.30	Lecture 8: Vigilance Reporting – an Agency perspective <ul style="list-style-type: none">• Common issues and pitfalls to avoid	MHRA TBC
10.30 – 11.00	Refreshment Break	
11.00 – 12.30	Lecture 9: Post Market Surveillance - Legal Considerations <ul style="list-style-type: none">• Criminal and administrative liabilities• Considerations for listed companies Public Relations	Grant Castle Covington & Burling LLP Confirmed in person
12:30 – 13:30	Lunch	
13.30 – 15.00	Lecture 10: Field Safety Corrective Actions - Legal Considerations <ul style="list-style-type: none">• Field safety corrective actions• Safeguard measures Product liability	Grant Castle Covington & Burling LLP confirmed
15.00 – 15.30	Close of Module	