Module 16: Post Market Surveillance and Vigilance for Medical Devices
2-4 & 7 September 2020

Location: to be delivered online

Module Leader: Samantha Cooper

Date: Wednesday 2nd September

Time	Activity	Speaker
13:00	**Registration and Welcome & 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

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Date: Thursday 3rd September 2020

Time	Activity	Speaker
09:30 – 10:30	Lecture 3: The Role and Responsibility of Notified Bodies in Vigilance and Post Market Surveillance	Theresa Jeary Regulatory and Scientific Affairs
10.30 – 11.00	Refreshment Break	
11.00 – 12.00	Lecture 4: Post Market Surveillance and Corrective and Preventive Actions:	James Pink NSF
12.00 – 13.00	Lunch	
13.00 – 14.30	Lecture 5: Risk Management/Risk Assessment	David Roe Novartis

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Date: Friday 4th September 2020

Time	Activity	Speaker
09.30 – 10.30	Lecture 6: Periodic Safety Update Report • SSCP Guidance 2.12 1 rev 8	To be announced
10.30 – 11.00	Refreshment Break	
11.00 – 12.30	Lecture 7: Post Market Clinical Follow Up • Plan • Implementation Overview • PMCF studies PMCF evaluation report	To be announced
12:30 – 13:30	Lunch	
13.30 – 15.30	Case study: Vigilance Reporting	John Deavin

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Date: Monday 7th September 2020

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 MDs	Tony Sant MHRA
10.30 – 11.00	Refreshment Break	
11.00 – 12.30	Lecture 8: 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 9: 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	