

Module: 16 - Post Market Surveillance and Vigilance for Medical Devices

Date: 28/04/2026-30/04/2026



Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

Module Leaders: Paul Risborough

Day 1: 28/04/2026

Time	Activity	Speaker
13:00 – 13:30	Registration Welcome & Introduction to the Module	Paul Risborough
13:30 – 14:15	Lecture 1: MDR Update <ul style="list-style-type: none">• Status of the MDR transition• MDR improvements, COM (2025) 1023, changes and their potential impact• Harmonization of standards• Common specifications• EUDAMED go live• AI, the MDR and regulatory compliance	Paul Risborough Edwards Lifesciences IHFM
14:15 – 15:00	Lecture 2: An Introduction to PMS <ul style="list-style-type: none">• An introduction to PMS, the basics• The challenges of PMS• MDCG and other guidance• PMS tools	Paul Risborough Edwards Lifesciences IHFM
15:00 – 15:30	Refreshment Break	
15:30 – 17:00	Lecture 3: The role and responsibilities of Notified Bodies in Vigilance and Post-market Surveillance <ul style="list-style-type: none">• Roles and responsibilities in reporting and assessing incidents; Healthcare Provider, Patient, Manufacturer, EU Authorized Representative, Importer, Distributor, Notified Body, Competent Authorities, and EU Commission.• NB oversight of manufacturers' vigilance and PMS systems• Evaluation of manufacturers' reporting processes, including how serious incidents and trends are identified and escalated.• Verification that post-market surveillance plans and activities are implemented effectively and continuously.• Assessment of the manufacturer's corrective and preventive actions (CAPA) in response to post-market findings.• Review of documentation provided to the Notified Body, including PMS reports, PSURs, and vigilance data.• Reporting vigilance via EUDAMED.• The use of IMDRF problem reporting codes.• Case studies/examples, good and bad.	Vishal Thakker BSI Head of UK Approved Body, Regulatory Services (Medical Devices)

Module: 16 - Post Market Surveillance and Vigilance for Medical Devices

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Day 2: 29/04/2026

Time	Activity	Speaker
08:45 – 09:00	Introduction to Day 2 and review of Day 1	Paul Risborough
09:00 – 10:00	Lecture 4: Post-market surveillance requirements under the MDR (EU) 2017/745 <ul style="list-style-type: none">In depth review of the MDR PMS requirements.	Paul Risborough Edwards Lifesciences IHFM
10:00 – 10:30	Refreshment Break	
10:30 – 11:30	Lecture 5: UDI and Traceability in Healthcare <ul style="list-style-type: none">UDI OverviewEUDAMED<ul style="list-style-type: none">Actor RegistrationUDI/Device Registration ModuleNotified Bodies and CertificatesMarket SurveillanceVigilanceClinical Investigations / Performance Studies	TBC
11:30 – 12:30	Lunch	
12:30 – 13:30	Lecture 6: Post Market Surveillance - Legal Considerations <ul style="list-style-type: none">Criminal and administrative liabilitiesConsiderations for listed companiesPublic Relations	Grant Castle Covington & Burling LLP
13:30 – 14:00	Refreshment Break	
14:00 – 15:00	Lecture 7: Field Safety Corrective Actions - Legal Considerations <ul style="list-style-type: none">Field safety corrective actionsSafeguard measuresProduct liability	Grant Castle Covington & Burling LLP
15:00 – 16:00	Lecture 8: Post-market surveillance, risk assessment and corrective/preventative action <ul style="list-style-type: none">The basics of risk management and its use in PMS.Trending of PMS data and setting action thresholds.Corrective and preventative action (CAPA).	Paul Risborough Edwards Lifesciences IHFM
16:00 – 16:15	Refreshment Break	

Module: 16 - Post Market Surveillance and Vigilance for Medical Devices

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16:15 – 17:00

Case Study: Assessing complaints

- Teams of two
- Twelve scenarios
- Reportable incident, or not
- Reporting timescales
- CAPA requirements

David Mandley

Principal Regulatory
Consultant, NAMSA

Module: 16 - Post Market Surveillance and Vigilance for Medical Devices

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Day 3: 30/04/2026

Time	Activity	Speaker
08:45 – 09:00	Introduction to Day 3 and Review of Day 2	Paul Risborough
09:00 – 10:00	Lecture 9: Vigilance Reporting – an Agency perspective <ul style="list-style-type: none">• Common issues and pitfalls to avoid• Reporting of serious incidents and field safety corrective actions• Transparency schemes• Borderline issues on Medical Devices• Enforcement action• Case examples	Sarah El Amin MHRA
10:00 – 10:30	Refreshment Break	
10:30 – 11:30	Lecture 10: Periodic Safety Update Report (PSUR) <ul style="list-style-type: none">• The purpose and importance of a PSUR• MDR PSUR requirements• What are the reporting timescales• What are the inputs and outputs of a PSUR	David Mandley Principal Regulatory Consultant, NAMSA
11:30 – 12:30	Lunch	
12:30 – 13:30	Lecture 11: Post-market Clinical Follow-up (PMCF) <ul style="list-style-type: none">• What is PMCF, where does it fit in the overall PMS system• Real-world data, its importance in medical device safety• When is PMCF required, when can it be stopped• Common challenges in designing a PMCF study	David Mandley Principal Regulatory Consultant, NAMSA
13:30 – 14:00	Refreshment Break	
14:00 – 15:00	Real World Examples and Quiz <ul style="list-style-type: none">• PMS Plan• PMCF Plan• PSUR• Quick Fire Quiz!	Paul Risborough Edwards Lifesciences IHFM
15:00 – 15:30	Close <ul style="list-style-type: none">• Written assignment briefing• Any other questions• Feedback forms	Paul Risborough Edwards Lifesciences IHFM