

# 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:** Tuesday 28/04/2026

Time	Activity	Speaker
13:00 – 13:30	<b>Registration</b> <b>Welcome &amp; Introduction to the Module</b>	<b>Paul Risborough</b>
13:30 – 14:15	<b>Lecture 1: MDR Update</b> <ul style="list-style-type: none"><li>• Status of the MDR transition</li><li>• MDR 2.0 improvements, COM (2025) 1023, changes and their potential impact</li><li>• Harmonization of standards</li><li>• Common specifications</li><li>• EUDAMED go live</li><li>• AI, the MDR and regulatory compliance</li></ul>	<b>Paul Risborough</b> Edwards Lifesciences IHFM
14:15 – 15:00	<b>Lecture 2: An Introduction to PMS</b> <ul style="list-style-type: none"><li>• An introduction to PMS, the basics</li><li>• The challenges of PMS</li><li>• MDCG and other guidance</li><li>• PMS tools</li></ul>	<b>Paul Risborough</b> Edwards Lifesciences IHFM
15:00 – 15:30	<b>Refreshment Break</b>	
15:30 – 17:00	<b>Lecture 3: The role and responsibilities of Notified Bodies in Vigilance and Post-market Surveillance</b> <ul style="list-style-type: none"><li>• Roles and responsibilities in reporting and assessing incidents; Healthcare Provider, Patient, Manufacturer, EU Authorized Representative, Importer, Distributor, Notified Body, Competent Authorities, and EU Commission.</li><li>• NB oversight of manufacturers' vigilance and PMS systems</li><li>• Evaluation of manufacturers' reporting processes, including how serious incidents and trends are identified and escalated.</li><li>• Verification that post-market surveillance plans and activities are implemented effectively and continuously.</li><li>• Assessment of the manufacturer's corrective and preventive actions (CAPA) in response to post-market findings.</li><li>• Review of documentation provided to the Notified Body, including PMS reports, PSURs, and vigilance data.</li><li>• Reporting vigilance via EUDAMED.</li><li>• The use of IMDRF problem reporting codes.</li><li>• Case studies/examples, good and bad.</li></ul>	<b>Purvi Patel</b> BSI Regulatory Lead – Global Regulatory Compliance Team

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**Day 2:** Wednesday 29/04/2026

Time	Activity	Speaker
08:45 – 09:00	<b>Introduction to Day 2 and review of Day 1</b>	<b>Paul Risborough</b>
09:00 – 10:00	<b>Lecture 4: Post-market surveillance requirements under the MDR (EU) 2017/745</b> <ul style="list-style-type: none"><li>In depth review of the MDR PMS requirements.</li></ul>	<b>Paul Risborough</b> Edwards Lifesciences IHFM
10:00 – 10:30	<b>Refreshment Break</b>	
10:30 – 11:30	<b>Lecture 5: UDI and Traceability in Healthcare</b> <ul style="list-style-type: none"><li>UDI Overview</li><li>EUDAMED<ul style="list-style-type: none"><li>Actor Registration</li><li>UDI/Device Registration Module</li><li>Notified Bodies and Certificates</li><li>Market Surveillance</li><li>Vigilance</li><li>Clinical Investigations / Performance Studies</li></ul></li></ul>	<b>Shweta Agarwal</b> Edwards Lifesciences
11:30 – 12:30	<b>Lunch</b>	
12:30 – 13:30	<b>Lecture 6: Post Market Surveillance - Legal Considerations</b> <ul style="list-style-type: none"><li>Criminal and administrative liabilities</li><li>Considerations for listed companies</li><li>Public Relations</li></ul>	<b>Grant Castle</b> Covington & Burling LLP
13:30 – 14:00	<b>Refreshment Break</b>	
14:00 – 15:00	<b>Lecture 7: Field Safety Corrective Actions - Legal Considerations</b> <ul style="list-style-type: none"><li>Field safety corrective actions</li><li>Safeguard measures</li><li>Product liability</li></ul>	<b>Grant Castle</b> Covington & Burling LLP
15:00 – 16:00	<b>Lecture 8: Post-market surveillance, risk assessment and corrective/preventative action</b> <ul style="list-style-type: none"><li>The basics of risk management and its use in PMS.</li><li>Trending of PMS data and setting action thresholds.</li><li>Corrective and preventative action (CAPA).</li></ul>	<b>Paul Risborough</b> Edwards Lifesciences IHFM
16:00 – 16:15	<b>Refreshment Break</b>	
16:15 – 17:00	<b>Case Study: Assessing complaints</b>	<b>David Mandley</b>

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

Principal Regulatory  
Consultant, NAMSA

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Day 3: Thursday 30/04/2026

Time	Activity	Speaker
8:45 – 09:00	<b>Introduction to Day 3 and Review of Day 2</b>	<b>Paul Risborough</b>
09:00 – 10:00	<b>Lecture 9: Vigilance Reporting – an Agency perspective</b> <ul style="list-style-type: none"><li>• Common issues and pitfalls to avoid</li><li>• Reporting of serious incidents and field safety corrective actions</li><li>• Transparency schemes</li><li>• Borderline issues on Medical Devices</li><li>• Enforcement action</li><li>• Case examples</li></ul>	<b>Sarah El Amin</b> MHRA
10:00 – 10:30	<b>Refreshment Break</b>	
10:30 – 11:30	<b>Lecture 10: Periodic Safety Update Report (PSUR)</b> <ul style="list-style-type: none"><li>• The purpose and importance of a PSUR</li><li>• MDR PSUR requirements</li><li>• What are the reporting timescales</li><li>• What are the inputs and outputs of a PSUR</li></ul>	<b>David Mandley</b> Principal Regulatory Consultant, NAMSA
11:30 – 12:30	<b>Lunch</b>	
12:30 – 13:30	<b>Lecture 11: Post-market Clinical Follow-up (PMCF)</b> <ul style="list-style-type: none"><li>• What is PMCF, where does it fit in the overall PMS system</li><li>• Real-world data, its importance in medical device safety</li><li>• When is PMCF required, when can it be stopped</li><li>• Common challenges in designing a PMCF study</li></ul>	<b>David Mandley</b> Principal Regulatory Consultant, NAMSA
13:30 – 14:00	<b>Refreshment Break</b>	
14:00 – 15:00	<b>Real World Examples and Quiz</b> <ul style="list-style-type: none"><li>• PMS Plan</li><li>• PMCF Plan</li><li>• PSUR</li><li>• Quick Fire Quiz!</li></ul>	<b>Paul Risborough</b> Edwards Lifesciences IHFM
15:00 – 15:30	<b>Close</b> <ul style="list-style-type: none"><li>• Written assignment briefing</li><li>• Any other questions</li><li>• Feedback forms</li></ul>	<b>Paul Risborough</b> Edwards Lifesciences IHFM