TT LifeSciences
LIVE INTERACTIVE CONTENT

6th – 8th October 2026
NH Amsterdam Schiphol Airport Hotel
Hybrid Conference

10th Edition

EUROPEAN MEDICAL DEVICE & DIAGNOSTICS PMSV & QARA CONFERENCE

A DUAL TRACK CONFERENCE

From Inspection Readiness to Lifecycle Compliance

Unified QARA and PMSV Expertise High Impact Learning Elite Peer Exchange

www.medtechpms.com | www.medtechqara.com

CONFERENCE OVERVIEW

The 10th Edition European Medical Device & Diagnostics QARA &PMSV Conference marks a significant milestone, bringing regulatory strategy, quality governance, and post market surveillance together within one unified forum. The 2026 edition is designed to deliver integrated, cross functional learning and a comprehensive view of compliance, product safety, and lifecycle oversight.

- Navigating evolving MDR and IVDR regulatory expectations
- Strengthening proactive, intelligence driven risk and quality management
- Enhancing post market surveillance and vigilance maturity
- Improving inspection readiness and regulatory alignment
- Showcasing real world case studies and practical compliance frameworks
- Drivingcollaborationacross regulatory, quality, and vigilance leadership

WHY ATTEND

Gain actionable regulatory and surveillance insights

Strengthen signal detection, complaints, and risk frameworks

Learn from proven vigilance case studies

Benchmark maturity and connect with industry peers

Enhance inspection readiness and compliance consistency

WHO SHOULD ATTEND

- Post Market Surveillance and Vigilance
- Regulatory Affairs and QARA
- Quality Assurance and Audit Readiness
- Product Safety and Risk Management
- Clinical Evaluation and Medical Affairs
- Complaint Handling and Signal Detection
- Digital PMS and Data Analytics
- Notified Bodies and Regulatory Authorities
- Legal and Compliance

WHAT MAKES THIS CONFERENCE UNIQUE

Unified Platform integrating PMSV and QARA expertise

Execution Focused Workshops addressing real compliance challenges

Regulatory & Industry Insights from global leaders and authorities

Real Case Intelligence featuring transformation journeys and practical lessons

Curated Peer Networking enabling senior level collaboration and partnerships

WHAT PAST ATTENDEES SAY:

“

For me, attending the conference was very interesting and insightful—it was my first one. What I enjoyed the most was the networking during workshops and coffee breaks. People were more open and willing to share in those informal moments.

Senior Post-market Surveillance & Vigilance technician,
B. BRAUN SURGICAL, S.A.

“

Being part of the PMSV conference highlighted the power of bringing industry experts together to shape the future of data-driven, innovative and patient-focused vigilance.

Vigilance Reporting Manager,
JOHNSON & JOHNSON

“

I really like the opportunities to ask questions from the noti ed bodies. I asked several questions about issues we have within our operations and got my answers. I love to network with professionals from other companies, hearing about their practices.

Clinical Affairs Specialist,
AEROGEN

ADVISORY BOARD MEMBERS

Markus Pöttker
Director, Global PMS
SMITH+NEPHEW

Sharon Perez
Vice President, Global MedicalSafety
NOVOCURE

Stephanie Berger
Director Global Post Market Surveillance
PHILIPS

Nunung Nur Rahmah
Head of Internal Clinical Team
DEKRA

Katharina Socher
Head of Product and Post Market Excellence
SIEMENS HEALTHINEERS

Ella Helgeman
Senior Director Global Regulatory Affairs
RADIOMETER

Adam Gregory
Head of Regulatory Affairs
COLOPLAST

Lyudmila Glushkova
Global Regulatory Affairs Director
HOYA SURGICAL OPTICS

Martin Geertsema
VP International QA RA
CONMED

Liz Gommans
Technical File Reviewer IVDR and RA Specialist
DEKRA CERTIFICATION B.V.

DISTINGUISHED SPEAKERS

Markus Pöttker
Director, Global PMS
SMITH+NEPHEW

Sharon Perez
Vice President, Global MedicalSafety
NOVOCURE

Stephanie Berger
Director Global Post Market Surveillance
PHILIPS

Nunung Nur Rahmah
Head of Internal Clinical Team
DEKRA

Katharina Socher-Wedel
Head of Product and Post Market Excellence
SIEMENS HEALTHINEERS

Sara Crocetti
Medical Device Manager Certification Division
BUREAU VERITAS ITALIA

Federica Malvaso
Post Market Surveillance & Vigilance Manager
ENOVIS

Julia Stindl
Head of Global Clinical Safety
NOVOCURE

Christian von der Grün
Director Post Market Surveillance
B. BRAUN GRUPPE

Jie Jia
Senior Medical Director
FRESENIUS KABI

Renea Olsen
Senior Post-Market Surveillance Manager, Scientific Affairs
3SHAPE

Ate Loonstra
Director of Clinical Affairs
PHILIPS

Maite Llacer
Sr Director Quality Compliance International
EDWARDS LIFESCIENCES

Pascal Smeets
Sr. Clinical Research Manager
MEDTRONIC

Lyudmila Glushkova
Global Regulatory Affairs Director
HOYA SURGICAL OPTICS

Martin Geertsema
VP International QA RA
CONMED

Liz Gommans
Technical File Reviewer IVDR and RA Specialist
DEKRA CERTIFICATION B.V.

Harsha Hosahallimath
Director of Quality
MEDLINE EUROPE

PRE- CONFERENCE WORKSHOP

6th OCTOBER 2026 TUESDAY

08:00 CET — REGISTRATION AND REFRESHMENTS

08:40 CET

PMSV TRACK

CHAIRPERSON'S WELCOME
REMARKS AND ICEBREAKER SESSION

LIMITED SEATS - ACCESS TO LIVE ATTENDEES ONLY SECUREYOUR SPOTTODAY!

QARA TRACK

CHAIRPERSON'S WELCOME
REMARKS AND ICEBREAKER SESSION

LIMITED SEATS - ACCESS TO LIVE ATTENDEES ONLY SECUREYOUR SPOTTODAY!

9:00 CET

WORKSHOP A

RECALLS IN PRACTICE: TRIGGERS, DECISION MAKING, AND REGULATORY COMMUNICATION

- Detecting true recall triggers through trending, signals, and Article 88 expectations
- Making defensible FSCA vs recall decisions under MDR pressure
- Defining recall class, scope, and timelines across markets
- Aligning authority, notified body, and customer communication

WORKSHOP A

EVIDENCE EXCELLENCE: STRENGTHENING TECHNICAL DOCUMENTATION TO AVOID CERTIFICATION REJECTION

- Building Annex II and III documentation that meets current NB expectations
- Addressing common rejection points across CER, risk, and PMS linkages
- Closing evidence gaps before submission, not during deficiency rounds
- Structuring clear, traceable, and defensible documentation for faster approvals

11:00 CET — NETWORKING COFFEE BREAK

11:30 CET

WORKSHOPS CHALLENGE
SIGNAL TO STRATEGY SIMULATION: PRIORITISING SAFETY SIGNALS UNDER REGULATORY PRESSURE

- Live simulation evaluating multiple emerging safety signals
- Real time decisions on reporting, escalation, and investigation actions
- Defining when signals require reporting vs monitoring
- How regulators assess signal justification, documentation, and next steps

WORKSHOPS CHALLENGE
NOTIFIED BODY AUDIT SIMULATION: RESPONDING TO CRITICAL FINDINGS

- Live MDR/IVDR audit simulation with critical findings
- Real-time responses to auditor challenges and evidence requests
- What de-escalates findings vs what makes them worse
- How Notified Bodies decide next steps and follow-up actions

PRE- CONFERENCE WORKSHOP

6th OCTOBER 2026 TUESDAY

12:30 CET

NETWORKING LUNCH BREAK

13:30 CET

WORKSHOP B

PMS FOR AI-ENABLED MEDICAL DEVICES STARTING AT R&D STAGE

- Embedding PMS, PMCF, and risk controls into AI design from day one
- Managing algorithm changes, drift, and regulatory impact post market
- Building traceable data pipelines for real world evidence and updates
- Navigating EU expectations for AI transparency and lifecycle control

WORKSHOP B

AUDIT READINESS BOOTCAMP: FROM MOCK AUDIT TO CAPA CLOSURE

- Simulating MDR and ISO 13485 audits with real findings and pressure scenarios
- Responding to auditor questions with clear, evidence-based justifications
- Converting findings into effective CAPAs, not superficial fixes
- Demonstrating CAPA effectiveness and system level closure to auditors

12:30 CET

CLOSING REMARKS

MAIN CONFERENCE

7th OCTOBER 2026
WEDNESDAY

DAY 1

	PMSV TRACK	QARA TRACK
08:00 CET	REGISTRATION AND REFRESHMENTS	
09:00 CET	CHAIRPERSON'S WELCOME REMARK & SPEED NETWORKING SESSION	CHAIRPERSON'S WELCOME REMARKS & SPEED NETWORKING SESSION
09:30 CET	DESIGNING SCALABLE PMS AND PMCF SYSTEMS ACROSS PORTFOLIOS, LEGACY DEVICES, AND GLOBAL MARKETS	GLOBAL REGISTRATION STRATEGIES ACROSS EMERGING MARKETS
10:00 CET	PMS PLANNING FOR AI-ENABLED DEVICES ACROSS THE POST-MARKET LIFECYCLE	USING PMS DATA TO SUCCESSFULLY TRANSITION LEGACY DEVICES TO MDR / IVDR
10:30 CET	SIGNAL DETECTION METHODOLOGIES, THRESHOLDS, AND ESCALATION LOGIC	BEYOND LEGACY: MANAGING THE LAST MDR MILE COMPLIANCE
11:00 CET	NETWORKING COFFEE BREAK	
11:30 CET	**PANEL DISCUSSION** MANAGING VIGILANCE OBLIGATIONS ACROSS THE EU, UK, US, CANADA, CHINA, AND OTHER MARKETS	**PANEL DISCUSSION** DO ALL NOTIFIED BODIES AUDIT THE SAME WAY? REALITY VS ASSUMPTIONS
12:15 CET	TRANSLATING POST MARKET DATA INTO DEFENSIBLE BENEFIT RISK DECISIONS	MEASURING QMS EFFECTIVENESS: KPIs REGULATORS ACCEPT
12:45 CET	NETWORKING LUNCH BREAK	
14:00 CET	ADDRESSING INTERPRETATION GAPS BETWEEN MANUFACTURERS, NOTIFIED BODIES, AND AUTHORITIES	FROM AUDIT FINDINGS TO SYSTEMIC FIXES: WHAT ACTUALLY WORKS
14:30 CET	LINKING COMPLAINTS, TRENDING OUTPUTS, CAPA DECISIONS, AND RISK FILE UPDATES	CAPA EFFECTIVENESS: WHY SYSTEMS FAIL IN AUDITS
15:00 CET	BUILDING PMS DATA ENVIRONMENTS THAT DRIVE DECISION MAKING	UKCA, CE & DUAL COMPLIANCE IN PRACTICE
15:30 CET	NETWORKING COFFEE BREAK	

INTERACTIVE ROUNDTABLE DISCUSSION

ACCESS TO LIVE ATTENDEES ONLY

Explore, Collaborate,&Innovate: Join Our InteractiveRoundtable Discussions!

Engage in dynamic conversations, share insights, and collaborate on innovative solutions. Each roundtable has up to 15 seats and operates on a first-come, first-served basis. Secure your spot now to ensure you don't miss out on your preferred topic!

Register now

	PMSV TRACK	QARA TRACK
16:00 CET	**ROUND TABLE 1** OPERATIONALISING PMS ACROSS GLOBAL MARKETS **ROUND TABLE 2** MANAGING DISTRIBUTORS AND THIRD PARTY PMS DATA **ROUND TABLE 3** USING AUTOMATION AND AI WITHOUT CREATING COMPLIANCE RISK **ROUND TABLE 4** INSPECTION READINESS AND DOCUMENTATION DEFENCE STRATEGIES	**ROUNDTABLE 1** SURVIVING UNANNOUNCED INSPECTIONS **ROUNDTABLE 2** MANAGING NOTIFIED BODY RELATIONSHIPS UNDER MDR **ROUNDTABLE 3** AI IN QA & RA: WHERE TO START — WHERE TO STOP **ROUNDTABLE 4** NB AUDIT PREPARATION: WORST CASES, LESSONS LEARNED & RECOVERY
17:15 CET	CLOSING REMARKS AND CONFERENCE DAY 1 CONCLUDES	

MAIN CONFERENCE

8th OCTOBER 2026 THURSDAY

DAY 2

08:30 CET — REGISTRATION AND REFRESHMENTS

	PMSV TRACK	QARA TRACK
08:50 CET	CHAIRPERSON'S WELCOME REMARK & SPEED NETWORKING SESSION	CHAIRPERSON'S WELCOME REMARKS & SPEED NETWORKING SESSION
09:00 CET	IMPLEMENTING TREND REPORTING AND SIGNAL DETECTION UNDER ARTICLE 88	MEASURING QMS EFFECTIVENESS: KPIs REGULATORS ACCEPT
09:30 CET	TRANSLATING POST MARKET DATA INTO MEANINGFUL BENEFIT RISK CONCLUSIONS	COST OF QUALITY VS SPEED TO MARKET
10:00 CET	PRACTICAL INTERPRETATION OF PMCF OBLIGATIONS AND COMMON INDUSTRY MISCONCEPTIONS	BUILDING C-LEVEL BUY-IN FOR QARA TRANSFORMATION

10:30 CET — NETWORKING COFFEE BREAK

	FIRESIDE CHAT	FIRESIDE CHAT
11:00 CET	COLLABORATING WITH NOTIFIED BODIES AND REGULATORY AUTHORITIES – BUILDING TRUST AND REDUCING PMS BOTTLENECKS	FROM AUDIT FAILURE TO INSPECTION EXCELLENCE
11:45 CET	REAL- WORLD POST MARKET DATA TO SUPPORT A WIDE VARIETY OF CLINICAL EVIDENCE NEEDS	IMPLEMENTING DIGITAL QMS ACROSS MULTIPLE SITES

12:15 CET — NETWORKING LUNCH BREAK

13:15 CET	MANAGING CONTINUOUS SOFTWARE UPDATES AND ADAPTIVE SYSTEMS POST MARKET	CYBERSECURITY & USABILITY: WHERE QARA OWNS THE RISK
13:45 CET	FSCA, RECALLS, AND POST MARKET CRISIS LEADERSHIP	AI THAT SURVIVED AN AUDIT: FROM VISION TO EVIDENCE

14:15 CET

BEYOND THE AGENDA

A candid closing conversation on what PMS and vigilance systems actually deliver today — versus what they were meant to achieve. This session challenges audit-driven approaches, surfaces blind spots in MDR implementation, and repositions PMS as product intelligence, not paperwork.

DISCUSSION STARTERS -

- Are we producing more PMS documentation but gaining less insight?
- Are PMS systems built for inspections rather than patient safety?
- Are we producing more PMS documentation but gaining less insight?
- Why do PMS gaps still surface during audits years into MDR?
- Are notified body PMS expectations truly aligned across Europe?
- Is AI strengthening surveillance — or introducing new compliance risk?

BEYOND THE AGENDA

An honest discussion on the sustainability of QARA under MDR and beyond. This session explores fatigue, over-compliance, digital trust gaps, and what may become the next regulatory pressure point after stabilisation.

DISCUSSION STARTERS -

- How sustainable is permanent inspection readiness for QARA teams?
- What risks are emerging from knowledge loss and weak succession planning?
- Are we producing more PMS documentation but gaining less insight?
- When does over-compliance increase audit exposure instead of reducing it?
- Do regulators trust digital evidence, dashboards and AI outputs?
- What is the next regulatory bottleneck after MDR stabilises?

15:00 CET — CLOSING REMARKS & CONFERENCE DAY 2 CONCLUDES

ABOUT TT LIFESCIENCES

Since 2016, TT LifeSciences has been a trusted leader in curating high-impact conferences exclusively for the medical device and diagnostics industry. Born out of a need for more relevant, insightful, and actionable education in tightly regulated sectors, TT LifeSciences has redefined what industry events should look like—focused, specialized, and designed with the delegate in mind.

Each conference is purpose-built and carefully curated to reflect the real-world challenges, innovations, and opportunities facing professionals in sales training, clinical education, regulatory affairs, and commercial strategy across Europe and beyond.

With operations in both the UK and Asia, TT LifeSciences has hosted over 100 specialized events and earned the trust of global medtech leaders. Its conferences bring together senior-level professionals to connect, collaborate, and drive lasting industry impact.

TT LifeSciences doesn't just run events—it builds communities, sparks meaningful dialogue, and helps delegates turn insight into action. It is where medical device leaders come to learn, lead, and shape the future.

FOR ANY SUPPORT OR ENQUIRIES,
FEEL FREE TO GET IN TOUCH WITH OUR TEAM

Speaking Opportunities

Shreya Yadav
Shreya.Yadav@ttlifesciences.com

Sponsorship Opportunities

Daniel Tena
daniel.tena@ttlifesciences.com

Delegate Opportunities

Aadi Shah
Aadi.shah@ttlifesciences.com