

Understanding How New Regulatory Requirements Will Affect Operations



ZIMMER BIOMET
Moving You Forward.™



Frank Moloney

Quality Assurance & Regulatory Affairs
Vice President, EMEA

Zimmer Biomet



Understanding How New Regulatory Requirements Will Affect Operations



The importance of post-market surveillance for ensuring device safety and performance.



Analyse how EU MDR and ISO 13485 shape the type, quality, and quantity of post-market data required.



Strategies for effectively integrating regulatory requirements into operational workflows.



Leveraging health data to enhance product performance and compliance.

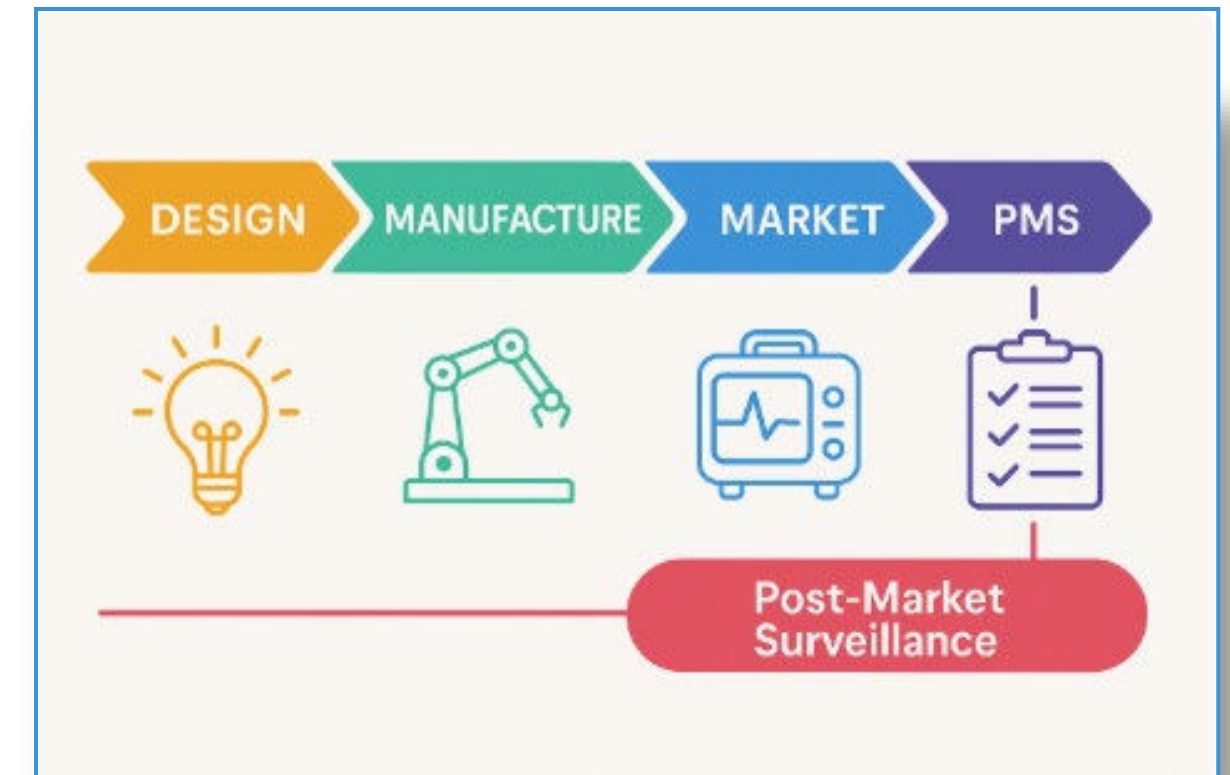


The Critical Role of Post-Market Surveillance (PMS)

PMS is essential for device safety and performance throughout the product lifecycle

EU MDR and ISO 13485 increase the focus on proactive, continuous monitoring

Robust PMS enhances patient safety, compliance, and competitive positioning



AI Opportunities in Complaint Handling

Structured but Manual: Current process relies heavily on human-driven decisions at each stage.

Data-Rich but Underused: Large volumes of complaints, but limited analytics beyond metrics.

Regulatory Risk: Delays or errors in reporting, classification, or root cause analysis can have compliance consequences.

Opportunity: AI can automate triage, detect patterns, and accelerate root cause analysis.

Goal: Improve speed, consistency, and quality of decision-making.



Post-Market Surveillance – From Reactive to Proactive



Reactive



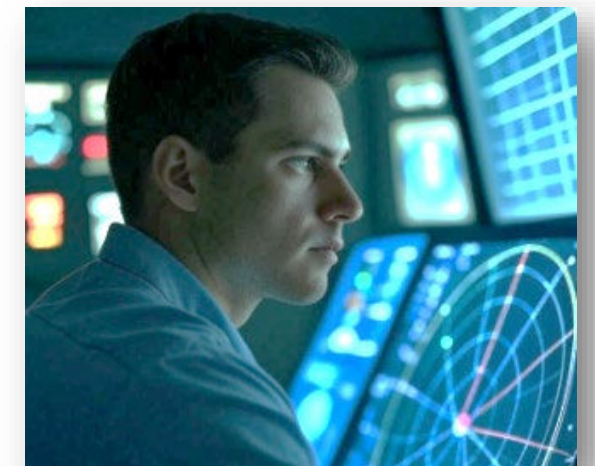
- Shift from issue-driven monitoring
- Customer complaints
- Adverse event reporting
- Product recalls
- Field safety corrective actions
- Vigilance reports



Proactive



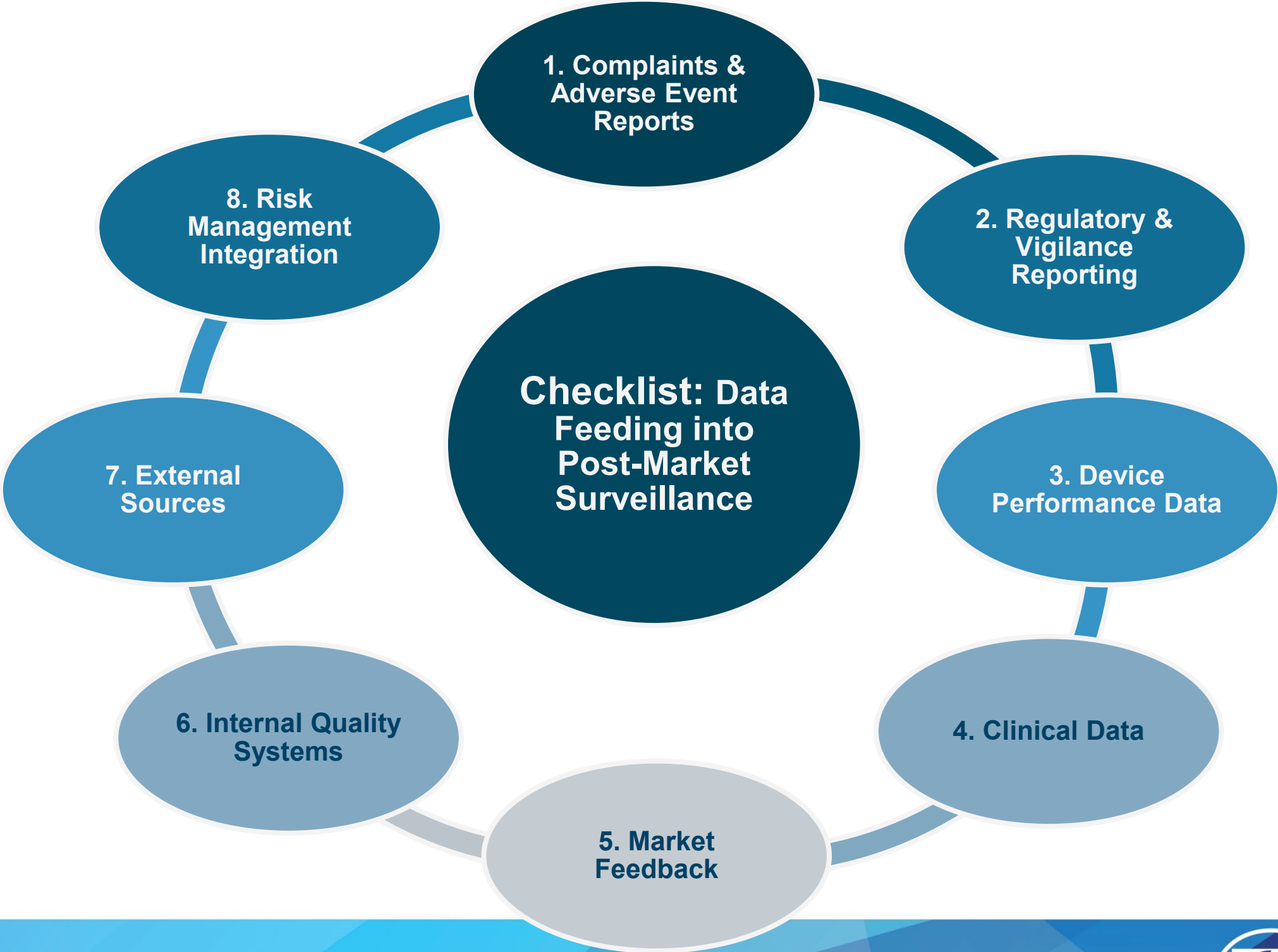
- Post market clinical studies
- Analysis of registry data
- Monitoring of training and support activities
- Live patient monitoring
- Literature review



Post-Market Surveillance – From Reactive to Proactive

Proactive Areas:

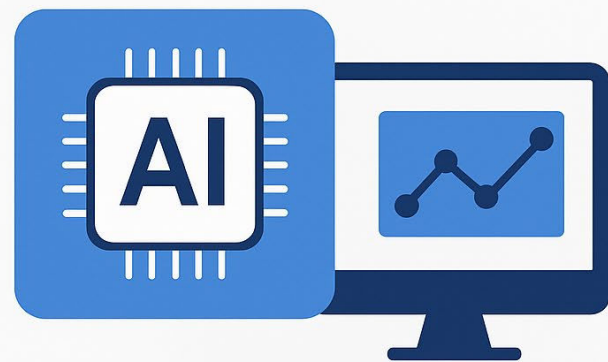
- Warranty claim data
- Maintenance and service records
- Distributor feedback
- Registry data
- Online review forums
- Health authority data bases



EU MDR – Raising the Bar on Post-Market Data

AI and Advanced Analytics in Post-Market Surveillance under EU MDR

AI and advanced analytics play a crucial role in enhancing post-market surveillance (PMS) under the EU Medical Device Regulation (MDR), enabling more efficient data collection, signal detection, and proactive risk management.



DATA
COLLECTION



SIGNAL
DETECTION



PROACTIVE
RISK
MANAGEMENT

Requires higher data granularity and clinical evidence.

Mandates tools like PMCF and PSUR for ongoing evaluation.

Demands continuous data collection under real-use conditions.



Automation Within Quality Today

Manual Data Collection

Report Forms

- Complaint forms
- Adverse event report forms
- Service or maintenance forms
- Incident report forms

Questionnaires

- Customer satisfaction surveys
- User feedback
- Healthcare provider questionnaire

Interviews

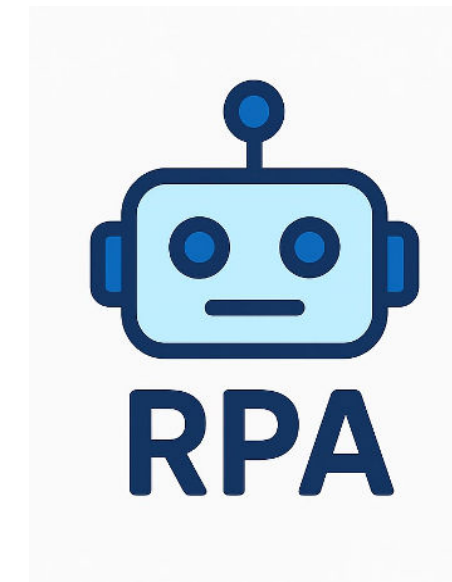
- Structured Interviews
- Semi-structured interviews
- Stakeholder interviews

Observations

- Site Visits
- Field service assessments
- Usability Testing
- Clinical observations

Paper systems, Excel, Data bases, macros, minitab.

Robotic Process Automation (RPA)

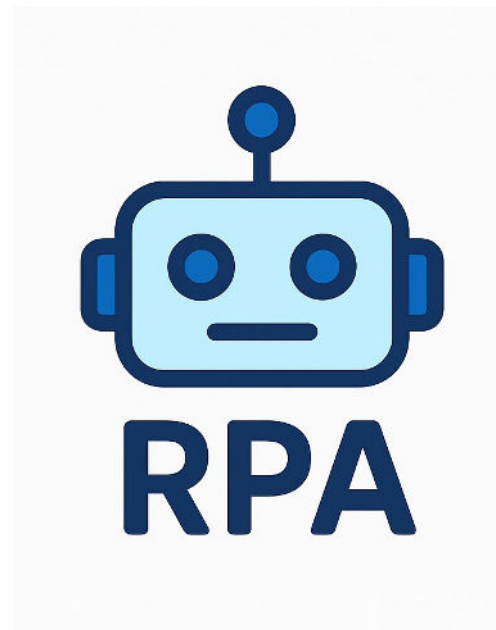


Software that **mimics** human actions to automate repetitive, **rule-based** tasks.



Automation Within Quality Today

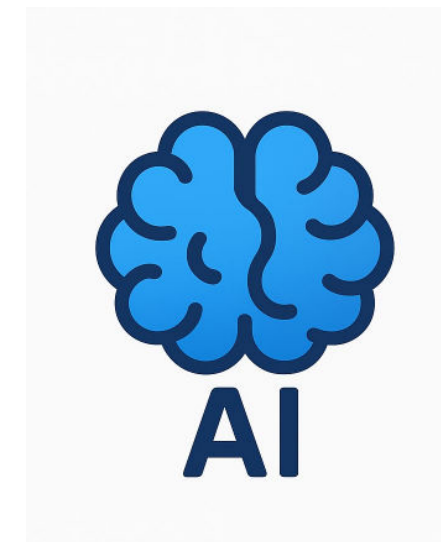
Robotic Process Automation (RPA)



Software that **mimics** human actions to automate repetitive, **rule-based** tasks.



Artificial Intelligence (AI)



Systems that can perform tasks typically **requiring** human **intelligence** (e.g., reasoning, learning, decision-making).



Health Data – mymobility & ZB Edge

ZBEdge

by  ZIMMER BIOMET

A suite of connected digital and robotic healthcare technologies designed to deliver actionable insights with the goal of improving outcomes



How Zimmer Biomet Addresses Today's Healthcare Challenges

- 1 Volumes
- 2 Efficiency
- 3 Outcomes
- 4 Experience

Value Areas

Engaged Patients



mymobility[®]



Direct-to-patients

- 1
- 2
- 4

Empowered Care Team

WalkAI[™]



OrthoIntel

ZIMMER BIOMET
Institute

- 3
- 4

Intelligent Operating Room



- 2
- 3
- 4

Smarter Execution

RAPID
RECOVERY[®]

ROSA[®]
Efficient Care

- 1
- 2
- 3
- 4

Data and Insight Platform

Platform

ZBEdge



Integrating Regulatory Requirements Into Operations



- **AI and advanced analytics**
 - Implement automated tools for real-time data collection and analysis.
 - Develop regulatory dashboards and alerts for early issue detection.
- **Align** product development and manufacturing with regulatory checkpoints.
- **Foster collaboration** between Regulatory, QA, R&D and Support teams.
- Conduct regular **training** on new regulatory expectations.

Has identified that during insertion of the catheter, the needle is slow to retract or fails to retract.

Complaint from a final user that informed us about experiencing temporarily burning sensation after using the product.

A recent software modification introduced to enhance application stability inadvertently caused unintended regressions in the user experience.



AI in Quality and Compliance



Boost Accuracy

Catch defects early, reduce human error.



Accelerate Decisions

Analyse root cause and risk instantly.



Predict Issues

Shift from reactive to predictive quality.



Strengthen Compliance

Enhance data integrity and traceability.



Cost

Efficiencies, overheads and data mining.



Q & A



THANK YOU!





ZIMMER BIOMET
Moving You Forward.™