empowerreg ai

# Navigating Postmarket Surveillance & Complaint Handling

*Practical Insights and Strategic Approaches*

# Certificate Status

**HAVE MDD-CERTIFIED DEVICES ON THE MARKET?**

Firms with medical devices that are currently certified under the Medical Device Directive (MDD)

**HAVE TRANSITIONED TO MDR CERTIFICATION?**

Firms that have successfully transitioned their devices to the new Medical Device Regulation (MDR) certification

**ANY CLASS I-ONLY MANUFACTURERS HERE?**

Firms that only manufacture Class I medical devices, the lowest risk classification

# Poll

# Workshop Objectives

1

### COMPARING MDR AND MDD: ELEVATED PMS EXPECTATIONS

Key differences between Medical Device Directive (MDD) and Medical Device Regulation (MDR), highlighting elevated Postmarket Surveillance (PMS) & Postmarket Vigilance (PMV) requirements under MDR.

2

### PMS BASICS AND OBLIGATIONS BY DEVICE CLASS

What's required and how PMS & PMV obligations scale—based on medical device class—higher-risk devices require more comprehensive PMS & PMV.

3

### COMPLAINT HANDLING AND INTEGRATING INTO PMS INPUTS

The importance of effective complaint handling processes and how they integrate as critical inputs into the overall PMS (& PMV) system.

4

### CURRENT RULES - VIGILANCE REPORTING & TRENDING

Current vigilance reporting requirements under MDR and the importance of analyzing vigilance data to identify trends, emerging safety issues, and feed into PMS reporting.

5

### PMS APPROACHES - PROACTIVE VS REACTIVE

Comparing and contrasting proactive and reactive approaches to PMS, highlighting the benefits of a proactive, integrated data-driven, PMS program.

6

### HARMONIZING REGULATIONS: EUMDR AND FDA CONVERGENCE

Global Harmonization aligns rules and brings the concept of an "integrated closed-loop" QMS lifecycle. Which naturally leads to automation in the Age of AI.

# EU MDR impact: The shift to “Proactive”

### REACTIVE PMS UNDER MDD

PMS programs were often complaint-driven, focused on adverse event reports and recalls when problems were exposed.

### STRUCTURED PMS UNDER MDR

MDR requires PMS to be planned, systematic, proactive, and documented as part of the QMS.

### FORMALIZED PMS SYSTEM AND PLAN

MDR formalizes the PMS system and plan, with specific expectations outlined in Annex III.

### FEEDBACK LOOPS TO KEY PROCESSES

MDR mandates explicit feedback loops from PMS to risk management, clinical evaluation, design, and CAPA.

**THE TRANSITION FROM MDD TO MDR HAS SIGNIFICANTLY RAISED THE BAR FOR POST-MARKET SURVEILLANCE, MAKING IT A MORE STRUCTURED, PROACTIVE, AND INTEGRATED PART OF MEDICAL DEVICE MANAGEMENT.**

# MDD → MDR: A Significant Increase In Regulatory Rigor

| | |
|---|---|
| ELEVATED EVIDENCE EXPECTATIONS | • Increased scrutiny: clinical evidence and postmarket data to demonstrate ongoing safety and performance |
| INCREASED TRANSPARENCY & OVERSIGHT | • Greater transparency in postmarket activities with mandatory reporting and regulatory oversight |
| TIGHTENED VIGILANCE & TREND REPORTING REQUIREMENTS | • Stricter vigilance reporting and analysis to identify emerging safety issues and trends |
| FORMALIZED POSTMARKET DOCUMENTATION & REPORTING | • Structured, standardized documentation and reporting of post-market activities |
| REQUIRED STRUCTURED, PROACTIVE PMS SYSTEM | • Mandatory implementation of a comprehensive, proactive post-market surveillance system |
| STRENGTHENED LIFECYCLE ACCOUNTABILITY | • Increased responsibility/accountability for device safety & performance throughout entire product lifecycle |

# Workshop Objectives 2

1

### COMPARING MDR AND MDD: ELEVATED PMS EXPECTATIONS

Key differences between Medical Device Directive (MDD) and Medical Device Regulation (MDR), highlighting elevated Postmarket Surveillance (PMS) & Postmarket Vigilance (PMV) requirements under MDR.

2

### PMS BASICS AND OBLIGATIONS BY DEVICE CLASS

What's required and how PMS & PMV obligations scale—based on medical device class—higher-risk devices require more comprehensive PMS & PMV.

3

### COMPLAINT HANDLING AND INTEGRATING INTO PMS INPUTS

The importance of effective complaint handling processes and how they integrate as critical inputs into the overall PMS (& PMV) system.

4

### CURRENT RULES - VIGILANCE REPORTING & TRENDING

Current vigilance reporting requirements under MDR and the importance of analyzing vigilance data to identify trends, emerging safety issues, and feed into PMS reporting.

5

### PMS APPROACHES - PROACTIVE VS REACTIVE

Comparing and contrasting proactive and reactive approaches to PMS, highlighting the benefits of a proactive, integrated data-driven, PMS program.

6

### HARMONIZING REGULATIONS: EUMDR AND FDA CONVERGENCE

Global Harmonization aligns rules and brings the concept of an "integrated closed-loop" QMS lifecycle. Which naturally leads to automation in the Age of AI.

# The PMS System

## PMS ELEMENTS

- PMS Plan (MDR Article 84 + Annex III): The blueprint
- PMS Report & PSUR
- PMV: Vigilance Reporting and Trending

## PMS PURPOSE

“”Actively and systematically gather, record, and analyze device data across its lifetime”

## MUST SUPPORT & CONNECT

- Root Cause Analysis, CAPA
- Risk Management
- Clinical Evaluation

**A harmonized, proactive PMS system can meet both current EU and upcoming US requirements with minimal duplication**

# PMS Requirements

### PMS WAS LESS STRUCTURED / LESS PROACTIVE UNDER MDD

Medical Device Directive (MDD) requirements for post-market surveillance (PMS) were less stringent. Reactive and unstructured PMS led to safety & performance issues.

### PMS MUST BE PLANNED, DOCUMENTED, PROACTIVE, AND SYSTEMATIC UNDER MDR

The Medical Device Regulation (MDR) emphasizes a more comprehensive, proactive, and structured approach to post-market surveillance.

### PMS AS AN INTEGRAL PART OF THE QMS UNDER MDR

The MDR requires post-market surveillance to be an integral component of the overall Quality Management System (QMS).


### PMS REQUIREMENTS MUST BE MET NOW

The MDR post-market surveillance requirements are in effect and must be implemented by device manufacturers immediately.

# PMS requirements by Device Class

**All devices: PMS plan + complaint handling + vigilance**

Class I: PMS Plan + PMS Report (no PSUR)

Class IIa/IIb: PMS Plan + PSUR (summary for IIa, full for IIb)

Class III: PMS Plan + PSUR submitted to NB + strong PMCF link

Visual: scaling pyramid (Class I → III)

empowerreg ai

# Specifics for Class I: PMS Plan & PMS Report (without PSUR)

**PMS Plan and Reports**

Class I devices require a Postmarket Surveillance Plan and “periodic reports” to ensure ongoing safety and performance

**Exemption from PSUR**

Class I devices are exempt from Periodic Safety Update Reports (PSUR) due to their lower risk profile

**Mandatory Vigilance Systems**

Vigilance and complaint handling systems remain mandatory to monitor device safety despite simplified reporting

# Workshop Objectives 3

1

### COMPARING MDR AND MDD: ELEVATED PMS EXPECTATIONS

Key differences between Medical Device Directive (MDD) and Medical Device Regulation (MDR), highlighting elevated Postmarket Surveillance (PMS) & Postmarket Vigilance (PMV) requirements under MDR.

2

### PMS BASICS AND OBLIGATIONS BY DEVICE CLASS

What's required and how PMS & PMV obligations scale—based on medical device class—higher-risk devices require more comprehensive PMS & PMV.

3

### COMPLAINT HANDLING AND INTEGRATING INTO PMS INPUTS

The importance of effective complaint handling processes and how they integrate as critical inputs into the overall PMS (& PMV) system.

4

### CURRENT RULES - VIGILANCE REPORTING & TRENDING

Current vigilance reporting requirements under MDR and the importance of analyzing vigilance data to identify trends, emerging safety issues, and feed into PMS reporting.

5

### PMS APPROACHES - PROACTIVE VS REACTIVE

Comparing and contrasting proactive and reactive approaches to PMS, highlighting the benefits of a proactive, integrated data-driven, PMS program.

6

### HARMONIZING REGULATIONS: EUMDR AND FDA CONVERGENCE

Global Harmonization aligns rules and brings the concept of an "integrated closed-loop" QMS lifecycle. Which naturally leads to automation in the Age of AI.

# Complaints per EU vs US

1

**The EU has more-rigorous rules**

2

**The US has more-rigorous rules**

3

**Both regulatory schemes require same connectivity to QMS Lifecycle**

**Poll**

# What is a Complaint?

## FDA Perspective

*“any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.”*

*- 21 CFR 820.3(b)*

## EU MDR Perspective

- *Does not provide a definition of complaint, but relies upon ISO 13485:2016 concepts*

  *“written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.”*

  *- 13485:2016, section 3.4*

# Complaint Management under EU MDR

## View complaints as PMS inputs

- No direct mention in Article 10, reliance on QMS
- MDCG 2025-10 gets explicit, describes complaints and user feedback as postmarket data to be *analyzed*
- PMS Plan must describe *how* feedback and complaints are handled
- Implicit expectation of risk-based triage for issue identification
- Complaint → risk assessment → CAPA → FSN/FSCA → risk management

empowerreg ai

# Be proactive with complaints

**Reactive Complaint Response**

Handling complaints as isolated incidents prevents recognition of similarities to identify trends and signals early

**Viewing Complaints as Part of A System**

Approach complaints as an information input to the device product lifecycle; think of how they will be evaluated through PMS

**Apply Adverse Event Codes**

Once segregated from Feedback, complaints should be coded using IMDRF Adverse Event Codes (more universal than MAUDE codes)

**Proactive Risk Assessment**

Connecting product risks to complaints as they come in helps to identify potential issues and supports effective, early mitigation

empowerreg ai

# Workshop Objectives 4

1

### COMPARING MDR AND MDD: ELEVATED PMS EXPECTATIONS

Key differences between Medical Device Directive (MDD) and Medical Device Regulation (MDR), highlighting elevated Postmarket Surveillance (PMS) & Postmarket Vigilance (PMV) requirements under MDR.

2

### PMS BASICS AND OBLIGATIONS BY DEVICE CLASS

What's required and how PMS & PMV obligations scale—based on medical device class—higher-risk devices require more comprehensive PMS & PMV.

3

### COMPLAINT HANDLING AND INTEGRATING INTO PMS INPUTS

The importance of effective complaint handling processes and how they integrate as critical inputs into the overall PMS (& PMV) system.

4

### CURRENT RULES - VIGILANCE REPORTING & TRENDING

Current vigilance reporting requirements under MDR and the importance of analyzing vigilance data to identify trends, emerging safety issues, and feed into PMS reporting.

5

### PMS APPROACHES - PROACTIVE VS REACTIVE

Comparing and contrasting proactive and reactive approaches to PMS, highlighting the benefits of a proactive, integrated data-driven, PMS program.

6

### HARMONIZING REGULATIONS: EUMDR AND FDA CONVERGENCE

Global Harmonization aligns rules and brings the concept of an "integrated closed-loop" QMS lifecycle. Which naturally leads to automation in the Age of AI.

# Postmarket Vigilance & Trending

### WHAT TRIGGERS REPORTING?

- Serious incidents (except “expected” side-effects), FSCAs

### EU TIMELINES (ARTICLE 87):

- Serious threat to public health - “immediately” (2 days)
- Death or unanticipated serious deterioration (10 days)
- Serious incident (15 days)

### US IN COMPARISON (21CFR PART 803)

- Unreasonable risk of substantial harm to public health (5 days)
- Deaths, serious injuries & malfunctions (30 days)
- Bulk reporting for similar, non-life-threatening events (monthly/quarterly)

# EU MDR Requirements That Apply Now

**POSTMARKET SURVEILLANCE**

PMS Plan (Article 84)

PMS Report (Article 85)

PSUR (Article 86)


**POSTMARKET VIGILANCE**

Reporting of SEs (Article 87)

Reporting of FSCAs (Article 87)

PSUR (Article 86)

**POSTMARKET TREND REPORTING**

Trend reporting (Article 88)

Report statistically significant increases in non-serious or expected incidents via Article 92

Define reporting periods and methods in the PMS Plan

**POSTMARKET DATA ANALYSIS**

Analysis of serious incidents & FSCAs (Article 89)

Investigate reported serious incidents (SAEs) promptly; assess the incident risk.

Report conclusions and CAs, share FSCAs & FSNs with customers & users.

**REGARDLESS OF CERTIFICATE TYPE OR DEVICE CLASS**

# Workshop Objectives 5

1

### COMPARING MDR AND MDD: ELEVATED PMS EXPECTATIONS

Key differences between Medical Device Directive (MDD) and Medical Device Regulation (MDR), highlighting elevated Postmarket Surveillance (PMS) & Postmarket Vigilance (PMV) requirements under MDR.

2

### PMS BASICS AND OBLIGATIONS BY DEVICE CLASS

What's required and how PMS & PMV obligations scale—based on medical device class—higher-risk devices require more comprehensive PMS & PMV.

3

### COMPLAINT HANDLING AND INTEGRATING INTO PMS INPUTS

The importance of effective complaint handling processes and how they integrate as critical inputs into the overall PMS (& PMV) system.

4

### CURRENT RULES - VIGILANCE REPORTING & TRENDING

Current vigilance reporting requirements under MDR and the importance of analyzing vigilance data to identify trends, emerging safety issues, and feed into PMS reporting.

5

### PMS APPROACHES - PROACTIVE VS REACTIVE

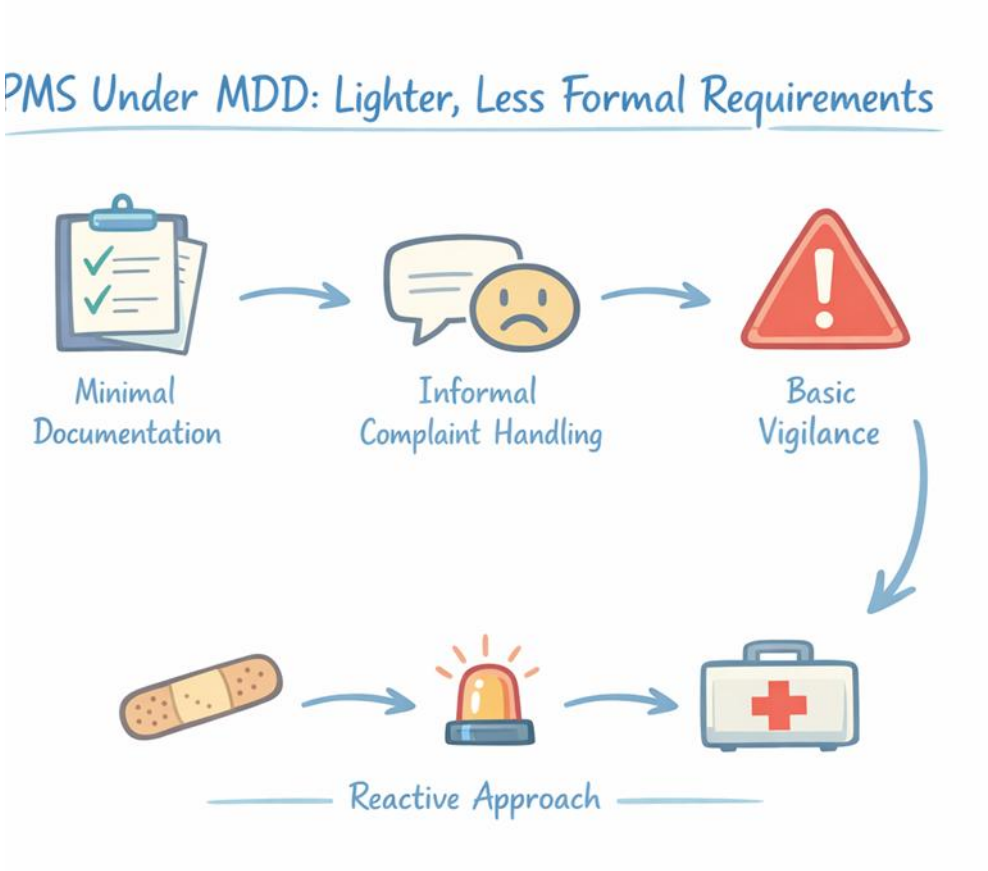
Comparing and contrasting proactive and reactive approaches to PMS, highlighting the benefits of a proactive, integrated data-driven, PMS program.

6

### HARMONIZING REGULATIONS: EUMDR AND FDA CONVERGENCE

Global Harmonization aligns rules and brings the concept of an "integrated closed-loop" QMS lifecycle. Which naturally leads to automation in the Age of AI.

# Reactive PMS Limitations




### REACTIVE PMS ACTIVITIES

PMS under MDD focused on reactive activities with minimal formal documentation, more reliance on vigilance

### LIMITED STANDARDIZATION

Minimal PMS processes and **no** mandatory Periodic Safety Update Reports (PSUR)

### RESTRICTED CHANGES FOR RISK MANAGEMENT

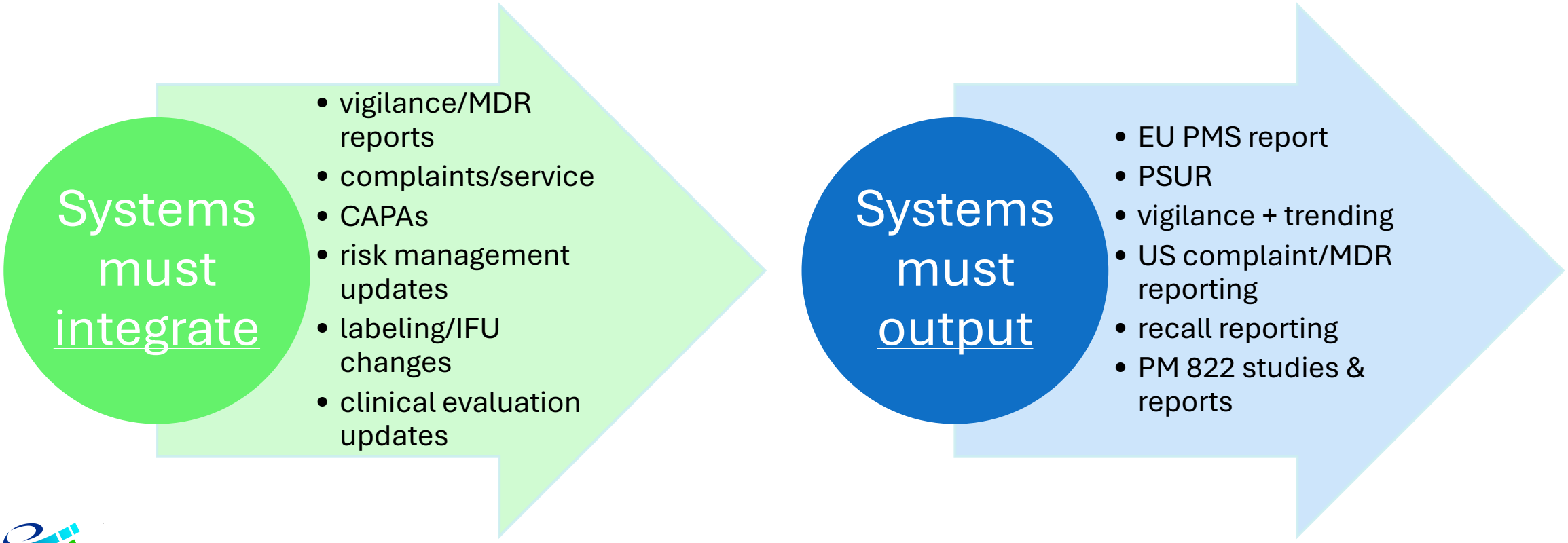
The approach offered few opportunities for proactive risk management or safety improvement

# Common goals between EU MDR and FDA QMSR

- Comprehensive system to collect experience from the use of the devices
- Reliance on ISO 13485:2016 as QMS model
- Required alignment with ISO 14971 for QMS and device risk integration
- Acceptance or adoption of IMDRF Adverse Event Codes for complaints
- Lifecycle management & data integration expectations

empowerreg ai

# Automated data integration: Single system, multiple outputs




empowerreg ai

# The rules of the game have changed: Automated data analysis now “required”

**Lifecycle expectations (MDCG + QMSR) require:**

- systematic data collection across sources
- continuous reassessment (benefit-risk/risk)
- trend detection and thresholds

**Manual processes break at scale; automation enables:**

- data consistency and integration
- consistent signal detection
- faster CAPA initiation
- traceability and auditability

empowerreg ai

# FDA moves from QSR to QMSR

## In force as of February 2, 2026


QMSR + ISO 13485:2016: Quality System harmonization

- ISO 13485:2016 (by reference)
- Plus FDA clarifications

Pursuing Global Harmonization

- Emphasis on data integration
- Aligns with IMDRF regulator goals
- Follow-on to MDSAP
- In preparation since 2019

Increased Expectations

- Feedback & complaint handling
- Analysis of data (trending & KPIs)
- Improvement through CAPA*
- Connections to risk management

# The compliance squeeze is getting tighter

Failure to act on these coordinated changes will lead to audit observations and loss of market access

**Loss of EU market access**

**FDA 483s, warning letters, recalls**


**Slowed innovation, negative media attention, loss of investor confidence**

# CASE STUDY: Transforming compliance *at speed*

**CUSTOMER**

## SME Dental Firm

*$34M Revenue Dental equipment manufacturer, drowning in data and manual workflows, struggling with compliance, facing loss of $7M including the loss of EU-market access due to non-compliance*

**FEEDBACK**

*This gave us back the EU market. It gets us to compliance both in USA and EU.*

Sr. Director of Quality

**RESULTS**

**10X**
Reduction in manual workflows

**10X**
Increase in analyst productivity

**80%**
Lower operational cost

**$6M Back in Play**
Access restored for the EU market

empowerreg ai

# Workshop Objectives 6

1

### COMPARING MDR AND MDD: ELEVATED PMS EXPECTATIONS

Key differences between Medical Device Directive (MDD) and Medical Device Regulation (MDR), highlighting elevated Postmarket Surveillance (PMS) & Postmarket Vigilance (PMV) requirements under MDR.

2

### PMS BASICS AND OBLIGATIONS BY DEVICE CLASS

What's required and how PMS & PMV obligations scale—based on medical device class—higher-risk devices require more comprehensive PMS & PMV.

3

### COMPLAINT HANDLING AND INTEGRATING INTO PMS INPUTS

The importance of effective complaint handling processes and how they integrate as critical inputs into the overall PMS (& PMV) system.

4

### CURRENT RULES - VIGILANCE REPORTING & TRENDING

Current vigilance reporting requirements under MDR and the importance of analyzing vigilance data to identify trends, emerging safety issues, and feed into PMS reporting.

5

### PMS APPROACHES - PROACTIVE VS REACTIVE

Comparing and contrasting proactive and reactive approaches to PMS, highlighting the benefits of a proactive, integrated data-driven, PMS program.

6

### HARMONIZING REGULATIONS: EUMDR AND FDA CONVERGENCE

Global Harmonization aligns rules and brings the concept of an "integrated closed-loop" QMS lifecycle. Which naturally leads to automation in the Age of AI.

# Global harmonization & IMDRF: Why it matters

International Medical Device Regulators Forum increasingly influences:

- the momentum for global harmonization (since the days of GHTF)
- convergence across all major (& most minor) regulators
- Essential Principles & “state of the art”
- reporting data elements
- adverse event terminology (complaint coding)

Why we should care:

- consistent coding improves trending, tracing, comparability, and cross-market reporting quality

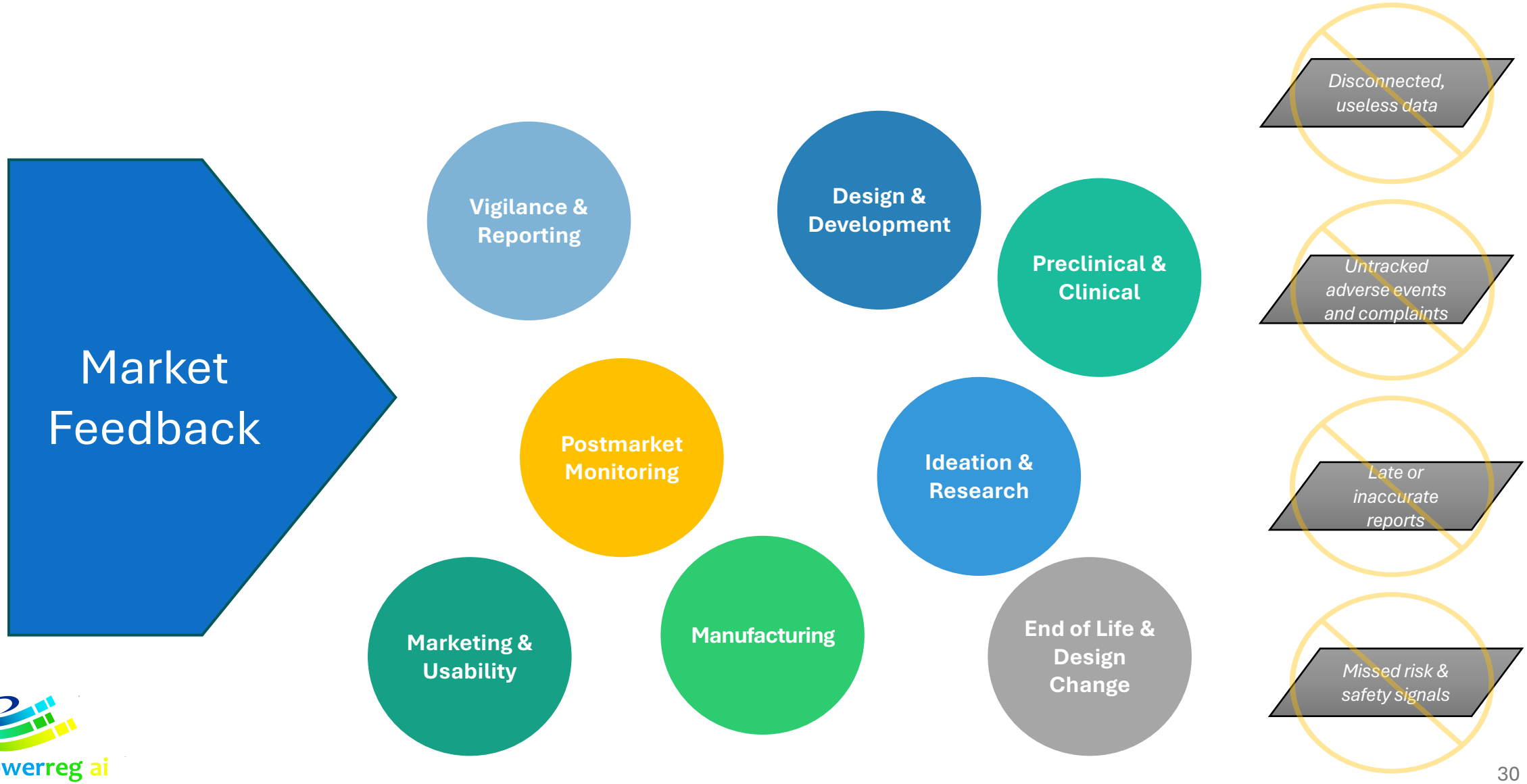
empowerreg ai

# What “integrated lifecycle evidence” looks like

- Intended use + claims + context of use
- Requirements + risk controls linked to the rest of the QMS
- Design/implementation changes (what changed, why, by whom)
- Change impact assessment (safety, performance, bias, cybersecurity, clinical impact)
- V&V decisions (with rationale & test evidence + acceptance criteria)
- Postmarket monitoring (drift, anomalies, complaints, usability issues)
- CAPA linkages when issues arise
- A QMS with controlled changes, backed by traceable data

empowerreg ai

# Siloed feedback fails—and RISK escalates




empowerreg ai

# Feedback data integrated into the product lifecycle


*Integrated data crates product and system risk reductions*

empowerreg ai

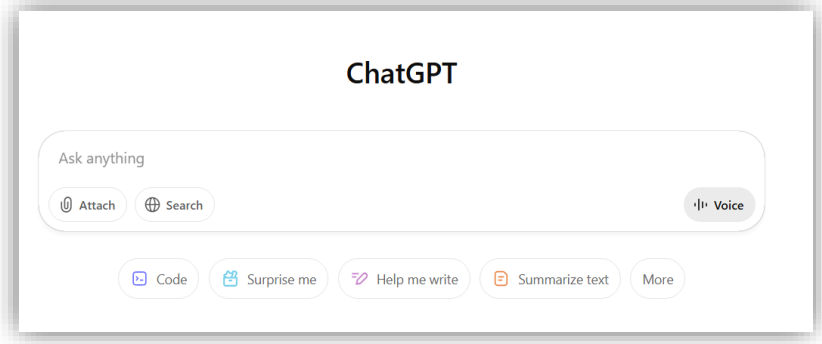
# The solution is a CMPMS™ to supplement eQMS

- Complaint Management Postmarket Surveillance System
- CMPMS as the operational “engine” for:
  - evidence capture → analysis → decisioning
  - CAPA initiation + effectiveness checks
  - audit trail and cross-market reporting readiness
- What regulators are looking for
  - closed loops
  - thresholds/indicators and rationale
  - documented decisions and timely reporting
  - traceability of actions to signals and risk updates

empowerreg ai

# Why public AI GPTs with LLMs won't work

## What off-the-shelf GPTs do not have




Diverse Data

Product Hub

Specialized Models

Privatized Learning

Automation with Human-in-the-loop

Integrated Workflows

Assurance

## We provide an integrated CMPMSTM

Dynamic Domain-Specific Knowledge Graphs

Custom Reasoning Engine

empowerreg.ai


MCP-driven Personalized Agentic Workflows


Custom Learning for Firms

empowerreg ai

empowerreg ai

# Building the World's Best AI-Native Compliance Platform

To transform postmarket surveillance and complaint management into a closed-loop system.

# Proposal to amend MDR/IVDR from the EU Commission

- Published proposal 16 Dec 2025 to simplify/reduce regulatory burden (amend the MDR & IVDR)
  - these are proposed changes
  - they do not change what is required today
- PMS, vigilance, and lifecycle obligations remain the current baseline
  - until proposal is adopted & implemented

empowerreg.ai

# Questions?

**Christine Zomorodian**
**CRIO**

35+ years in life sciences,
15 years consulting
Medical devices expert
UW & conference lecturer
Depth in global regulatory
Inventor of two novel clinical bioassays

Thank you for having us!

Contact us:

www.empowerreg.ai

christine@empowerreg.ai

**Surya Pathak**
**Co-Founder & CEO**

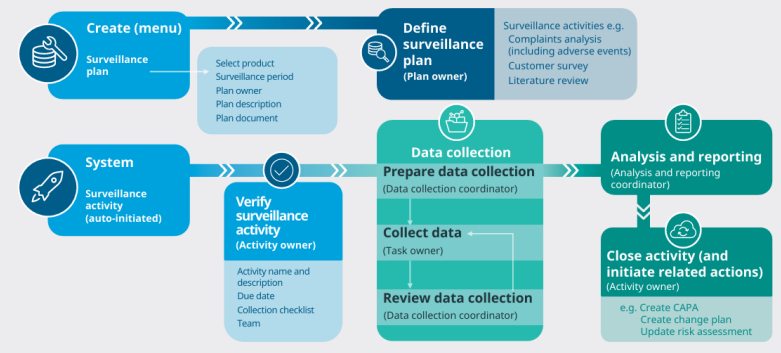
Tenured Professor at UW
UW Distinguished Research Award
Global lecturer & author
Extensive publications
Expert in Supply Chain, Technology Management, Six Sigma/Lean

# The future of compliance is here—introducing a new category: CMPMS™

## Disrupting the status-quo with an integrated CMPMS™

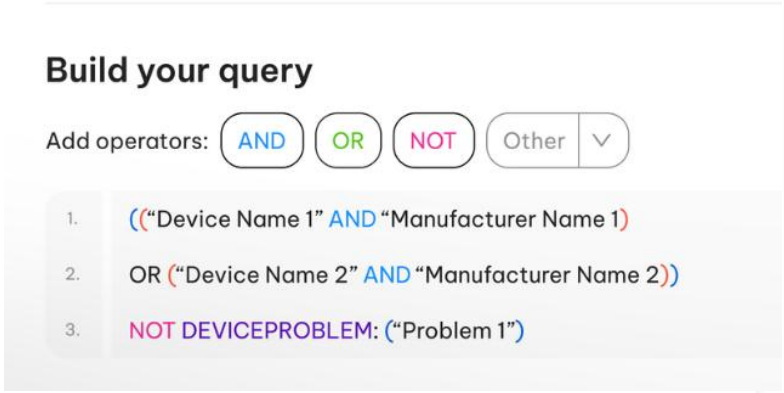
### Legacy Workflow

Script Based, Static



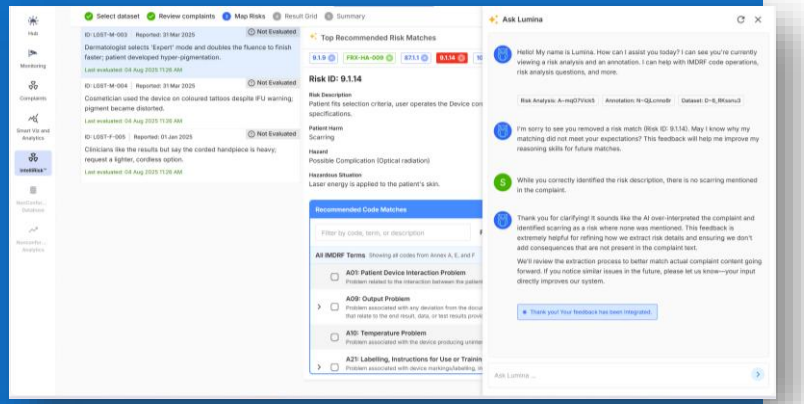

### Traditional SaaS

Human Operated, digitized workflows



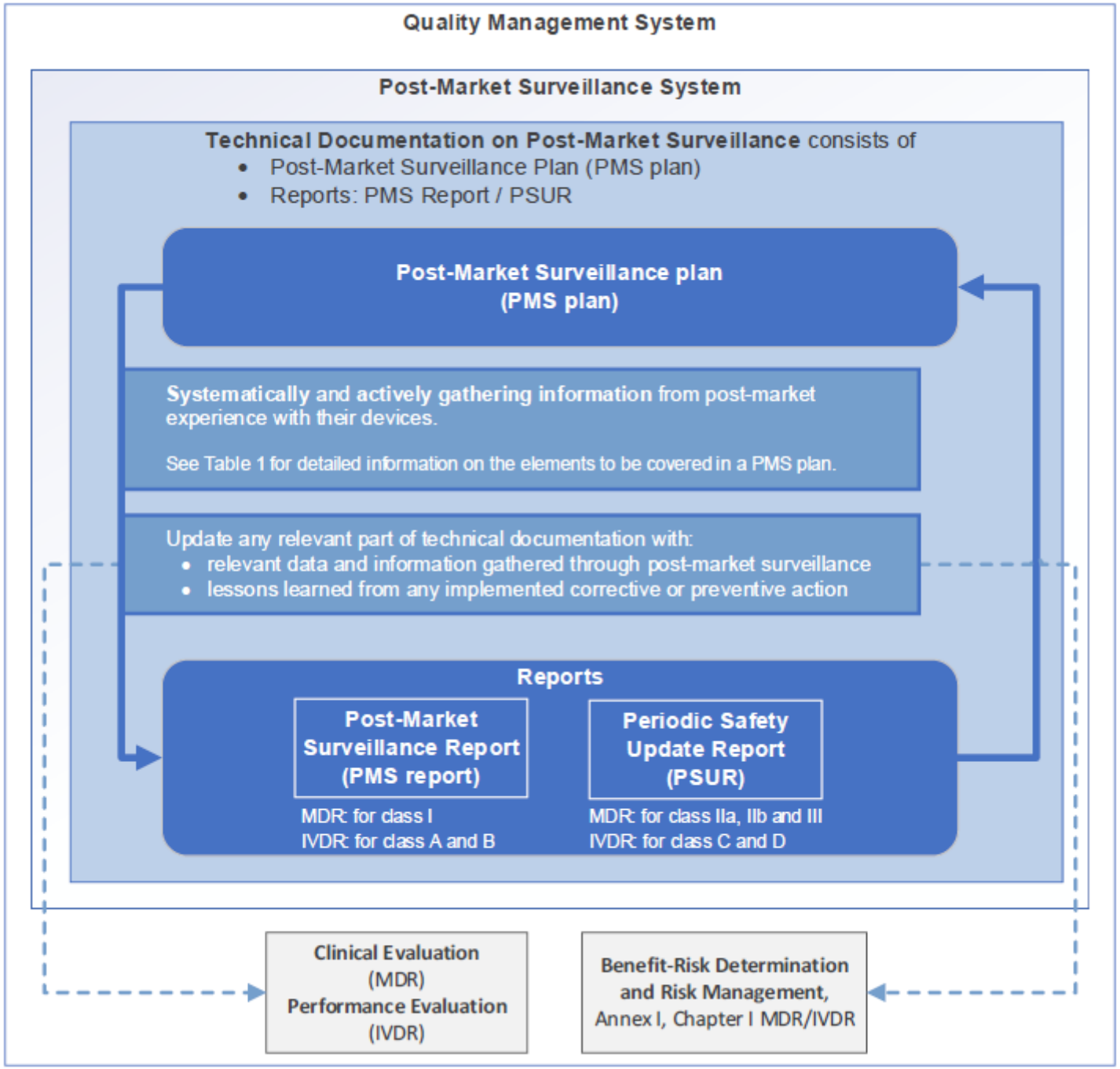

### empowerreg.ai

AI-native platform with HITL& learning



We own execution, get intelligence through data, and automate at scale – All with a Human-centered approach

Diagram from sect 3.1 of MDCG 2025-10 on PMS




empowerreg ai