

## SHOTUNE KNOWLEDGE SERIES

### Introduction 2: Building an Integrated PMS–PMCF–CER Engine for Portfolio Growth under EU MDR

#### Turning Post-Market Systems into a Commercialization Lever

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#### **Executive Context: 2026–2027 Is Not About Submission. It's About Sustainability.**

As EU MDR maturity deepens, manufacturers are discovering a structural reality: the bottleneck is no longer simply technical-documentation approval; it is evidence continuity across the product lifecycle.

Three pressures are converging: EUDAMED transparency expectations, Notified Body capacity constraints, and portfolio rationalization decisions that eliminate marginal SKUs lacking economic justification.

Under this environment, fragmented PMS, PMCF, and CER documentation is no longer sustainable.

The companies that win in 2026–2027 will operate a continuous evidence engine, not a document factory.

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#### **1. The Structural Problem: Siloed Compliance Architecture**

In many legacy systems, including large multinationals:

- PMS is managed as vigilance plus complaint trending.
- PMCF is executed as periodic checkbox studies.
- CER updates occur as reactive annual exercises.
- Risk-management files are updated independently.
- Market-access teams operate outside the regulatory-evidence loop.

The result:

- Lag between signal detection and design adaptation.
- Redundant clinical data generation.
- Weak linkage between real-world evidence and value proposition.
- Slow NB responses.
- Portfolio contraction driven by cost, not strategy.

Under MDR Articles 83–86, Annex III (PMS) and Annex XIV (clinical evaluation and PMCF), this architecture is inefficient and increasingly risky.

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#### **2. The Strategic Reframe: PMS as a Commercial Engine**

An integrated PMS–PMCF–CER system should do four things simultaneously:

- Detect safety signals early.
- Feed continuous clinical evidence into CER updates.
- Trigger risk and design optimization.
- Support reimbursement and health-economic positioning.

When properly structured, this system:

- Shortens iteration cycles.
- Protects CE-mark renewals.
- Reduces NB queries.
- Strengthens value dossiers for payers.

In other words: integrated regulatory continuity becomes protection of CE mark, pricing power, and growth runway — not just prevention of findings.

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### **3. Architecture of an Integrated Evidence Engine**

#### **A. Continuous PMS Signal Intelligence**

- Complaint trending explicitly linked to clinical outcomes.
- Statistical thresholds aligned with ISO 14971 risk controls.
- Closed feedback loops into design, labeling, and IFU changes.

#### **B. PMCF as Strategic Evidence Generation**

- PMCF plans aligned to residual risk and clinical-evidence gaps.
- Registry-based or real-world-data studies where feasible.
- Use of real-world evidence to sustain equivalence and support market-access claims.

#### **C. CER as a Living Analytical Platform**

- Dynamic, ongoing literature surveillance.
- Automatic integration of PMS and PMCF findings.
- Cross-portfolio evidence benchmarking to inform lifecycle and investment decisions.

#### **D. Executive Governance Overlay**

- Quarterly evidence-review boards.
- Cross-functional sign-off (Regulatory, Clinical, Quality, Commercial, Market Access).
- Portfolio-level risk and evidence heatmaps.

This is not document harmonization.  
It is evidence-systems engineering.

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## **4. 2026 Bottlenecks: Where Companies Are Getting Stuck**

### **EUDAMED Visibility**

Public-facing device and safety information increases scrutiny from:

- Competitors
- Payers
- Patients
- Investors

Inconsistent PMS trends are no longer invisible.

### **Notified Body Capacity Constraints**

Under MDR surveillance audits, NBs are:

- Requesting deeper PMCF justification.
- Challenging equivalence reliance.
- Scrutinizing statistical methodologies.
- Demanding clear evidence of risk linkage.

Companies without integrated systems experience:

- Repeat deficiency cycles.
- Increased audit durations.
- Escalating NB fees.

### **Portfolio Rationalization Under Pressure**

Many manufacturers are cutting SKUs because:

- PMCF costs exceed revenue.
- CER updates lack sufficient clinical depth.
- NB renewal costs are rising.

Companies with structured PMS intelligence, however, use evidence to:

- Demonstrate safety stability.
- Reduce unnecessary PMCF scope.
- Justify reimbursement discussions.
- Preserve high-margin products.

The difference is governance maturity.

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## **5. How an Integrated System Protects Revenue**

When PMS, PMCF, CER, and Risk Management operate as one engine:

## **Revenue Protection**

- Faster NB responses reduce time-at-risk.
- Stronger evidence supports price defense and tender success.
- Lower risk of forced discontinuations and market withdrawals.

## **Accelerated Iteration**

- Design updates driven by real-world trends, not anecdotes.
- Shorter post-market CAPA cycle times.
- Safer, more competitive next-generation products.

## **Investor Confidence**

Private-equity and strategic acquirers are increasingly assessing:

- PMS signal stability.
- PMCF cost trajectory.
- CER robustness.
- Lifecycle-evidence scalability.

An integrated evidence engine improves valuation multiples because it reduces regulatory volatility.

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## **6. What This Looks Like at Enterprise Scale**

### **For Large Manufacturers (Multinational MedTech)**

- Centralized evidence dashboards across franchises and regions.
- Cross-portfolio CER harmonization and standard analytics.
- PMCF prioritization models based on risk and revenue.
- AI-assisted signal detection and literature monitoring, where validated.

### **For Growth-Stage or PE-Backed Companies**

- Lean PMS frameworks with real statistical rigor.
- Early PMCF planning embedded in clinical-development strategy.
- CER authorship integrated with market-access and value narratives.

Different scale. Same architecture.

SHOTUNE designs the same core system in enterprise-grade and “right-sized” forms, depending on where the business is in its growth and investment cycle.

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## **7. Strategic Recommendations for 2026–2027**

- Stop managing PMS as vigilance-only.

- Redesign PMCF plans around strategic evidence gaps, not generic templates.
- Convert CER updates into quarterly analytical exercises, not annual paperwork.
- Establish an Evidence Governance Board with cross-functional accountability.
- Link regulatory-evidence dashboards to portfolio-management and investment reviews.

If your PMS system cannot answer:

- Which products are statistically drifting?
- Where are our highest residual-risk exposures?
- Which SKUs are revenue-positive but evidence-negative?
- How quickly can we respond to an NB major finding?

Then you do not have a system.  
You have documents.

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### **Closing Thought**

Under EU MDR, compliance is no longer static approval.  
It is continuous justification of market presence.

Organizations that treat PMS–PMCF–CER as a cost center will shrink.  
Organizations that treat it as a structured intelligence engine will:

- Protect revenue.
- Accelerate innovation.
- Strengthen payer positioning.
- Increase enterprise value.

This is the lens SHOTUNE brings to EU MDR: treating evidence not as paperwork, but as an enterprise asset that protects EBITDA and valuation.

Respectfully,

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