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Connected Evidence

Why Post-Market Surveillance Is Becoming a Commercial Advantage

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Two decades at the intersection of Risk, Supply Chain, and AI.

FOUNDER & CEO

Surya Pathak

empowerreg · Health Safety Intelligence

Professor
University of Washington, School of Business

Former CEO
CQUESTIP

WHAT WE BUILD

AI-native systems for post-market intelligence

Helping medical device manufacturers turn fragmented post-market data into Connected Evidence — and into commercial advantage.

RESEARCH FOUNDATION

Two decades of supply chain risk & operations

Bridging academic research with applied AI for medical device safety — alongside global manufacturers building real infrastructure.

WHAT IT PROTECTS

Brand · Regulators · Time to market

Building the infrastructure that protects brand, satisfies regulators, and accelerates time to market across the Total Product Life Cycle.

What is the most expensive moment in a medical device company’s life?

Gladys Knepper

1931 — June 2024

She Died At 93 When Her Pacemaker Battery Failed.

The manufacturer had seen the failures in factory tests for years. The recall came six months after her death.

Recall expanded three times since December 2024.

Source: New York Times investigation, March 2026.

The Signals Existed.

Nothing connected them in time.

832	02	1.6m
Injuries	Deaths	Devices Recalled

How expensive was this recall?

Gladys Is Not An Outlier.

Most device related harm is not a single catastrophic event,
it is slow building patterns the system was not designed to catch.

1.7M+

Injuries

Potentially Linked To Medical Devices Over The Last Decade In The U.s.

83,000

Deaths

Potentially Linked To Medical Devices Over The Same Period.

$2B+

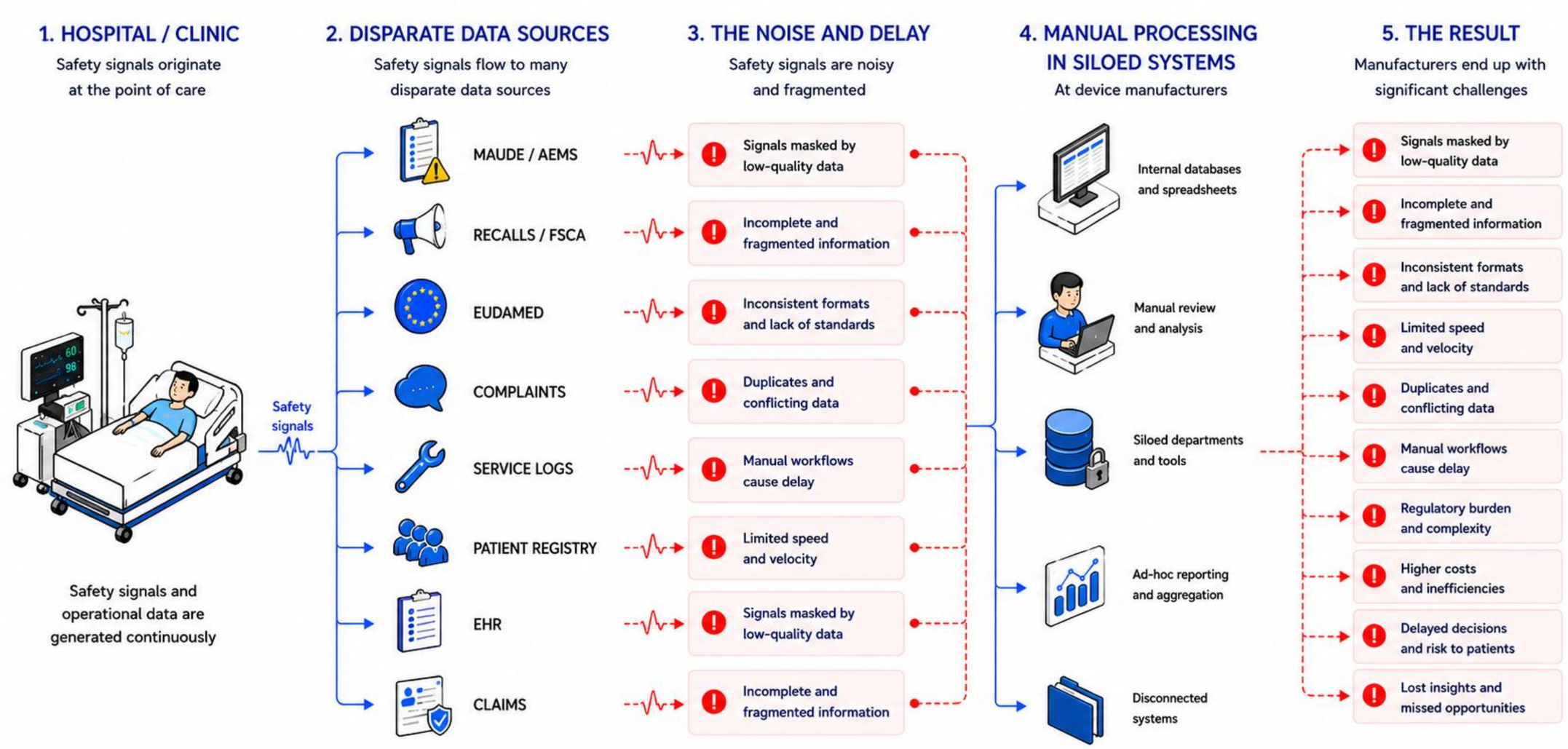
Recall Cost

Accolade Recall Alone — Monitoring, Replacements, Litigation, Lost Trust.

Each Failure Compounds. Harm → Reactive Recalls → Supply Chain Disruption → Billions Lost → Eroded Trust.

The Data Exists. Nothing Synthesizes It.

Signals exist across the supply chain but remain trapped in organizational silos until harm has already cascaded.



The missing piece is not more data. It's a system-level capability that closes the loop.

The PMS System.
It’s a global requirement.

01 · PMS ELEMENTS

The building blocks

PMS “System”
MDR Art. 83

PMS Plan
MDR Art. 84 + Annex III · The blueprint

PMS Report & PSUR
MDR Art. 85 & 86

PMV · Vigilance Reporting & Trending
MDR Art. 87 & 88

02 · PMS PURPOSE

What the regulation requires

“

Actively and systematically gather, record, and analyze device data across its lifetime.
— MDR, Article 83

03 · MUST SUPPORT & CONNECT

Where PMS plugs into the QMS

01 **Root Cause Analysis & CAPA**
Closing the loop on field signals

02 **Risk Management**
Hazards, harms, controls — live

03 **Clinical Evaluation**
Evidence that must stay current

Build it once, build it right: a harmonized, proactive PMS system can meet today's EU MDR and **tomorrow's US QMSR** with minimal duplication.

Consequences of non-compliance is severe

A 483 isn't a compliance event.

It's a market event.

Inspection observations and warning letters become public the moment they're filed. The market reads them before the company can respond.

Top 5 Device Mfg. · October 2025

−8.3%

Intraday drop on disclosure

FDA warning letter on three medical device manufacturing sites.

FDA CITED:
Complaint handling · Corrective & preventive action · Design validation · Adverse event reporting

Top 5 Device Mfg. · December 2021

−9%

Stock decline after letter

Warning letter to the diabetes group's mfg facility.

FDA CITED:
Risk assessment · Corrective & preventive action · Complaint handling · Adverse event reporting

Therapeutics Company · March 2026

−21%

Single day · ~$2B market cap lost

Warning letter on product promotion — followed by securities class actions.

FDA CITED:
Promotional claims · Disclosure timing · Investor communications

Sources: Bloomberg, MedTech Dive, MD+DI, FDA filings

In every case, the signal lived inside the company's own systems before the inspector found it. The market punishes the discovery — not the violation.

So where is the challenge?

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Imagine a Class III device maker with a global footprint.

On the same morning, the same device — implanted in two patients — fails.
Two call centers. Two handlers. Two languages. One device family. One risk file.

01 · EUROPE

08:42 CET · Barcelona

Surgeon reports unexpected device behavior mid-procedure. Call routed to the European call center.

HANDLER	LANGUAGE	CODED AS
Agent A	Spanish	Malfunction

02 · UNITED STATES

03:42 EST · Cleveland

Same moment, half a world away. Same device, different patient. The nurse calls the US support line.

HANDLER	LANGUAGE	CODED AS
Agent B	English	Use error

Will both events be recorded, triaged, investigated, and closed the same way, on time?

PMS used to be a linear workflow.

THE OLD MODEL

It isn't anymore.

The new reality.

Eight disconnected systems.

We don't lack data. We lack a way to make data speak the same language.
The signal often lives in the relationships between records — not inside any single one.

Complaints
Internal customer feedback

Adverse Events
Reportable clinical outcomes

Service Records
Field engineering signals

Risk Files
Hazards, harms, controls

CAPA
Action history & closure

Public Databases
Regulator, MAUDE, EUDAMED

Literature
Peer-reviewed evidence

Field Voices
Distributors, clinicians, patients

The burden falls entirely on the manufacturer.

Harmonize
Global medtech compliance spend

Track
Every signal, end to end

Interpret
Messy real-world data

Act
At the right moment

Justify
Every decision made

Prove
Consistency, years later

This is no longer a human-scale task.

Coding is not data entry.

It is how a real-world signal becomes a regulatory decision.

ONE EVENT · MANY LENSES

01	IMDRF code
02	Internal failure code
03	Clinical consequence
04	Risk-file linkage
05	Reportability decision
06	Brazil · US · EU view

And Then

Why?

Not What We Decided. Why We Decided. Why This Code. Why This Report. Why This Trend Escalated. Why This Risk Remained Acceptable?

QSR is now QMSR.
And the bar just moved.

IN FORCE

February 2, 2026

US medical devices

01 · WHAT CHANGED

Quality system harmonization

ISO 13485:2016
Now incorporated into US regulation by reference

Plus FDA clarifications
Where US requirements extend beyond ISO

Replaces 21 CFR Part 820 (QSR)
The framework US manufacturers grew up on

02 · WHY NOW

Global harmonization

A decade in the making —
in preparation since 2019.

- Emphasis on data integration
- Aligns with IMDRF regulator goals
- Follow-on to MDSAP
- **Convergence with EU MDR practice**

03 · WHAT IT EXPECTS

Increased expectations

01 **Feedback & complaint handling**

02 **Analysis of data**
Trending & KPIs

03 **Improvement through CAPA**

04 **Connections to risk management**

If you've built for EU MDR, you're closer to QMSR than you think. The harder regulator already paid for most of the work — now the question is whether your evidence speaks both languages.

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Modern PMS must preserve the reasoning trail.

STEP 1

Source Data

Where it came from

STEP 2

Classification Logic

How it was coded

STEP 3

Model Suggestion

If AI participated

STEP 4

Human Review

Who validated it

STEP 5

Final Decision

What we concluded

STEP 6

Justification

Why we acted

Without this trace, automation creates risk. With it, automation creates accountability.

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Risk is interpreted differently.

BR

Brazil · ANVISA

- Tecnovigilância framework
- Local reporting timelines
- Coding alignment in transition
- Distributor network signals

US

United States · FDA

- MDR reporting thresholds
- MAUDE public visibility
- Periodic / 5-day / 30-day rules
- Trending and CAPA expectations

EU

European Union · MDR

- EUDAMED vigilance modules
- PSUR & trend reporting
- Serious incident definitions
- PMCF integrated with PMS

The challenge is global consistency with local regulatory intelligence.

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Similar events.
Similar reasoning.

REVIEWER A · SÃO PAULO · TUESDAY

"

Codes the event as device malfunction. Not reportable.

REVIEWER B · LOS ANGELES · THREE WEEKS LATER

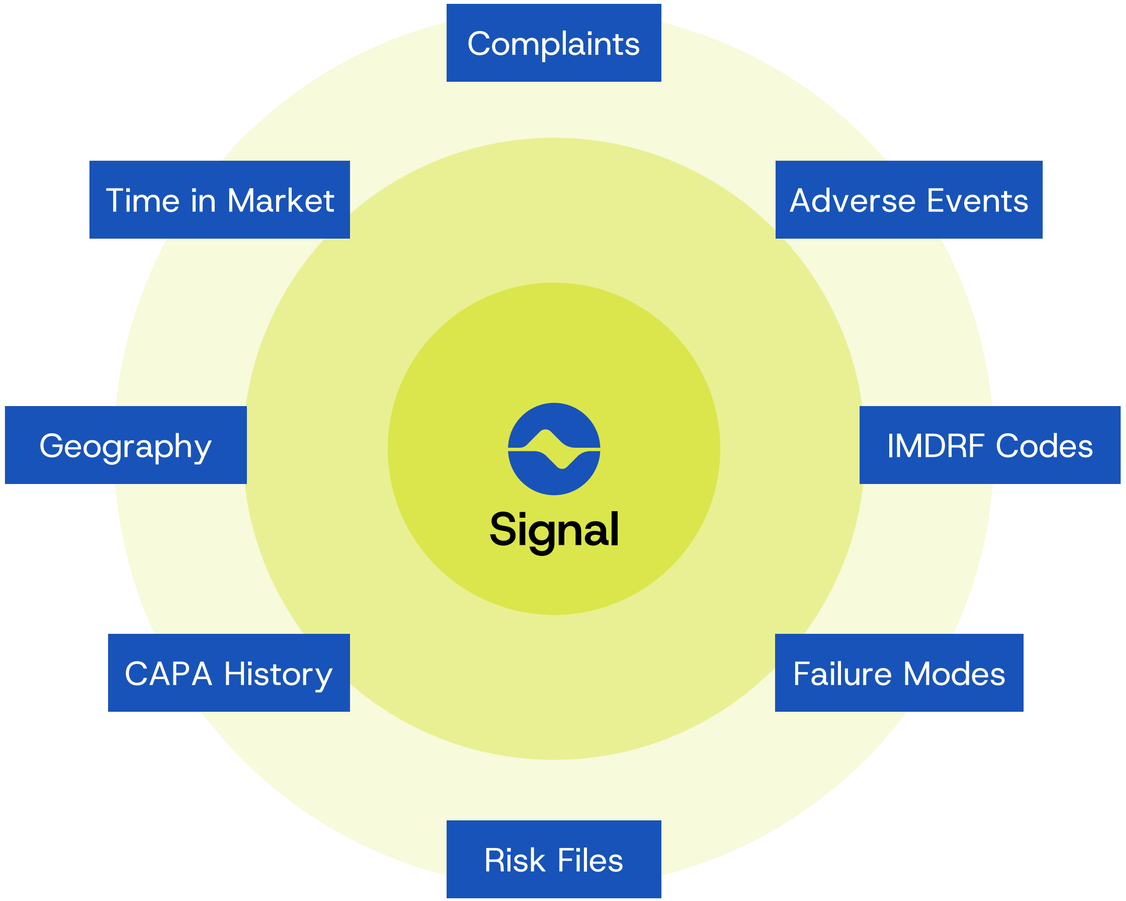
"

Codes the same event as use error. Reportable. CAPA opened.

AI MUST GIVE THE EXPERT INSTITUTIONAL MEMORY

- "We have seen events like this before."
- "They were coded this way."
- "This region treated similar events as reportable."
- "This decision differs from historical precedent."

Real safety signals live between systems.



A small uptick in any one of these may look harmless. Together, they tell a different story.

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Trend intelligence shouldn't end the process. It should drive it.

When a trend emerges

Connected Risk Signal

Detected, contextualized and explainable.

→

- Risk file review
- CAPA opened
- Regulatory reporting
- Labeling review
- Training
- Design feedback
- Investigation
- Management review

What is at stake? Where is the competitive advantage?

The compliance squeeze is getting tighter.
From both regulators. At the same time.

Failure to act on these coordinated changes leads to audit observations, market loss, and public scrutiny — often before the company even knows.

01 **Loss of EU market access**
EU MDR · Notified body action

02 **FDA 483s, warning letters, recalls**
Public the moment they're filed

03 **Slowed innovation, negative media, loss of investor confidence**
Compounds across product portfolio

CONSEQUENCE 01

EU Market

Access blocked

EU MDR · Notified body

FDA

WARNING

CONSEQUENCE 02

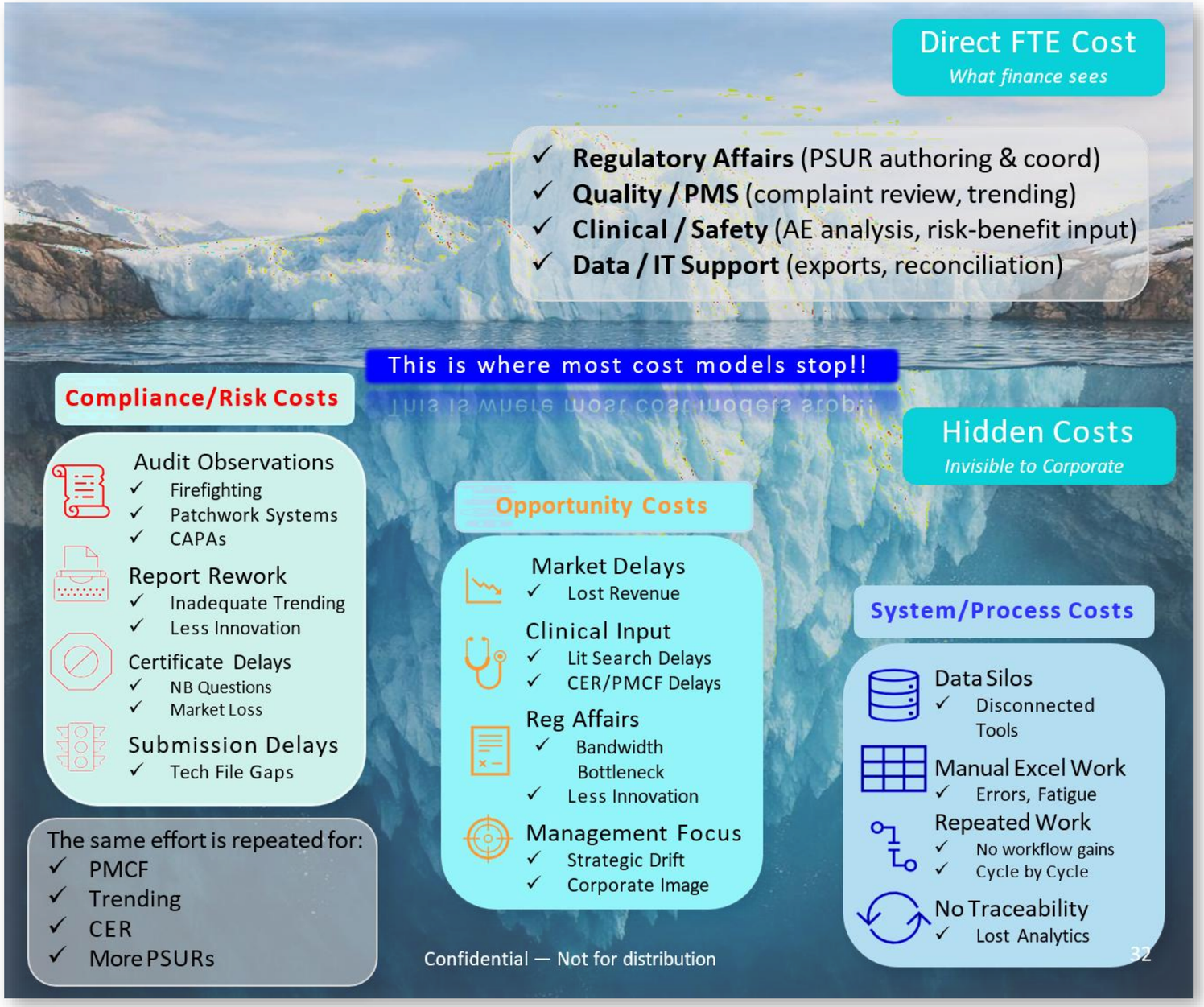
Public record.

Same day.

Form 483 · Recall · Letter

The consequences arrive in days. The signals that could have prevented them sit in your own data for months — **if you can connect them.**

Most manufacturers budget for the tip.
Then absorb the iceberg.



Quality failures don't stay in Quality.
They land on Sales, Marketing, and Innovation.

The cost of a PMS failure shows up in the QMS first — and on the P&L second. By the time it reaches the board, every commercial function is already paying.

01 · SALES

The pipeline pays first.

Procurement freezes
Hospitals & GPOs pause decisions on any active finding

RFP weaponization
Competitors cite your public letters in bid responses

Cycle elongation
Existing customers demand CAPA plans before re-orders

Channel friction
Distributors renegotiate terms — or quietly exit

02 · MARKETING

Brand equity, written down.

News-cycle damage
Years of trust hit in a single 24-hour window

Launch freezes
Active investigations halt campaign and PR plans

Budget displacement
Crisis comms spend crowds out demand generation

SEO long tail
Headlines outrank your owned content for years

03 · INNOVATION

R&D pays the remediation tax.

Engineering reallocated
Top people pulled to CAPA work, not new products

Submission delays
510(k) / PMA timelines slip while clearing backlog

Pipeline drift
Competitors close the gap while you remediate

Talent attrition
Best engineers leave during sustained fire drills

Connected Evidence isn't a quality investment. It's a commercial defense system — and the CFO is starting to see what the CRO already feels.

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Human-led. AI-enabled. Systems-preserved.

AI

- Listens
- Connects
- Suggests
- Explains

Humans

- Decide
- Provide feedback
- Train the system

Systems

- Preserve the trace
- Maintains consistency

AI is connective tissue, not a chatbot, not a dashboard, not a replacement.

CMPMS™ – Intelligent Post-Market Surveillance

Post-QMSR, manufacturers face a noisy, fragmented data landscape that masks signals and overwhelms analysts.

Risk Mapping & Analysis

AI-powered risk analysis for complaints and adverse events — dynamic risk profiling linked to product families

Reportability Decision Trees

Structured, defensible reportability workflows with automated decision trees for MDR, EU MDR vigilance, and Health Canada

Integration-Ready

Connects with existing QMS, ERP, and supply chain systems via open APIs — configurable SaaS architecture.

Global PMS & Vigilance

Multi-regulatory post-market surveillance and vigilance reporting: FDA, EU MDR, Health Canada, IMDRF

Report-Ready Assets

Auto-generated charts, tables, and graphics for PMS reports, PSURs, and regulatory submissions — export-ready

Complaint Management

AI-driven intake, triage, investigation, MDR reportability with IMDRF coding and human-in-the-loop automation.

Signal Detection & Trending

Emerging signal detection with trend analysis for complaints and risks across the device portfolio.

Outcome: Move from reactive compliance to proactive risk intelligence across every market you serve.

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The goal is not to automate responsibility.

The goal is to strengthen it.

Connect with us to modernize your journey

hello@empowerreg.ai

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