

Resilient Supply Chains in the Era of AI

Evidence from the Medical Device Industry

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

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CQUESTIP

WHAT WE BUILD

AI-native systems for post-market intelligence — turning fragmented field data into Connected Evidence.

RESEARCH FOUNDATION

Two decades of supply-chain risk & operations, bridging academic research with applied AI for device safety.

WHAT IT PROTECTS

The infrastructure that protects brand, satisfies regulators, and accelerates time to market.

THE SHARED RECKONING

Every industry has learned **the same lesson**
— the hard way.

A decade of shocks rewired how the world sources.

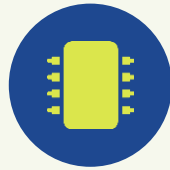


AUTOMOTIVE

45%

name supply-chain disruption their #1 concern — every year since 2022. Single-sourcing and just-in-time are being dismantled for nearshoring.

AMS / ABB Outlook 2025



SEMICONDUCTORS

~ 1/3

of global production could face copper supply disruption by 2035 as tariffs, export controls and climate fragment a once-seamless market.

SEMI · PwC, 2025



GLOBAL SHIPPING

+12%

global shipping cost in 2025 as Red Sea attacks since Oct 2023 reroute vessels around Africa — plus port cyberattacks and canal congestion.

SupplyChainBrain, 2025

The pattern: three decades of efficiency-driven globalization papered over a structural fragility. Disruption is no longer cyclical — it is the operating condition.

The model that ran the world for 30 years can't carry it forward.

THE OLD MODEL

- Just-in-time, minimal buffers
- Single-source, lowest landed cost
- Global concentration of capacity
- Visibility one tier deep
- Reporting monthly or quarterly

THE NEW MANDATE

- Engineered redundancy & buffers
- Diversified, nearshore sourcing
- Proximity and regionalization
- N-tier visibility across the network
- Continuous sensing, in real time

The path to resilience runs through visibility, agility, and collective intelligence – **monthly reporting cycles are now dangerously slow.**

SEMI, 2025

THE PIVOT

Healthcare is not exempt. It may be **the most exposed.**

One plant. 60% of America's IV fluids. One storm.



In September 2024, a levee breach flooded Baxter's North Cove facility in Marion, NC — the single site producing roughly 1.5 million IV bags a day. Hospitals nationwide were cut to 40% or less of their orders. Surgeries were postponed. The federal government invoked the Defense Production Act.

***The vulnerability wasn't the storm.** It was the concentration — and how long the signal took to resolve.*

~ 60%

of the U.S. IV-fluid supply,
from one site

7

global Baxter sites activated
to backfill

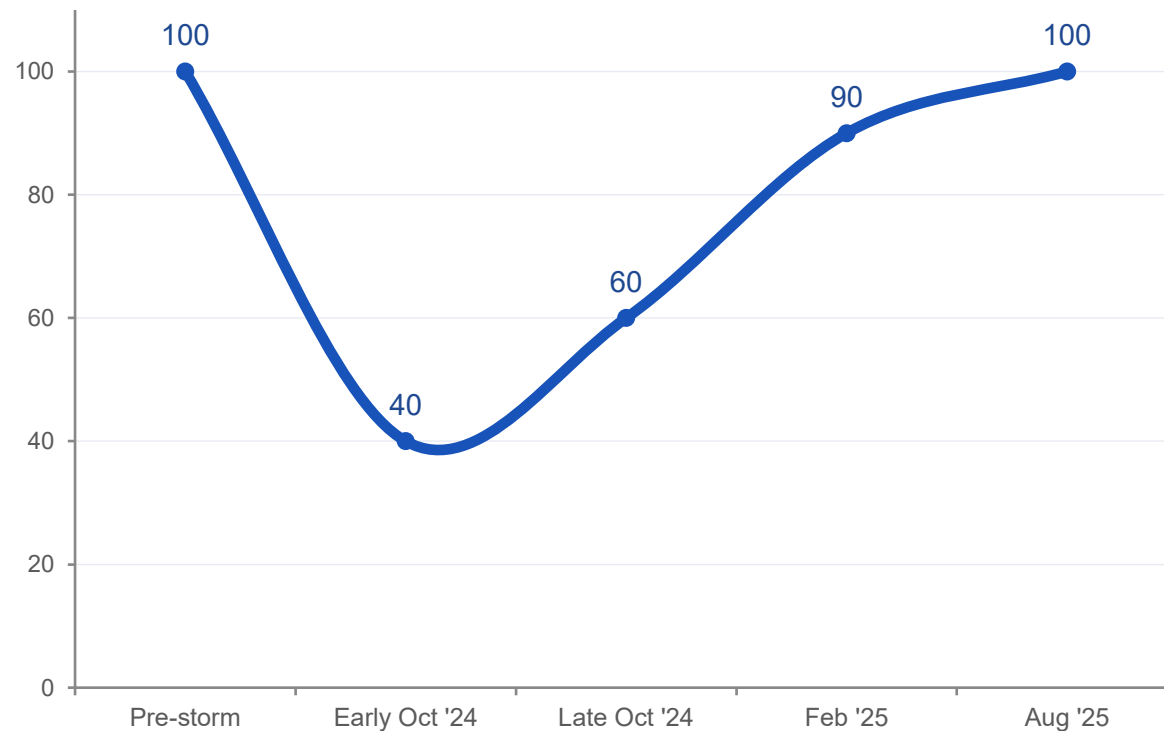
~ 11 mo

until FDA declared the
shortage over

Sources: American Hospital Assn.; FDA; Axios; AMA — 2024–2025.

A single point of failure, and a signal that resolved slowly.

U.S. hospital IV-fluid order fill rate



What resilience would have required



Redundancy by design

No single node should carry 60% of national supply with no warm alternative.



N-tier visibility

See the dependency before the disruption — not after hospitals start rationing.



Continuous sensing

Detect and act on the weak signal in days, not over an eleven-month recovery.

Devices have a second supply chain — the safety signal.

Helene exposed the physical supply chain. But the more chronic failure is informational: the device works in the field, generates warnings — factory tests, service logs, complaints — and the system never connects them in time. Most device harm is not one catastrophic event. It is slow-building patterns the system was never designed to catch.

***The signals existed.** Nothing connected them in time — until the recall, the headline, and the cascade.*

1.7M+

injuries reported in U.S. device adverse-event data over a decade

83,000

deaths potentially linked over the same period

\$2B+

cost of a single recall — replacements, litigation, lost trust

Harm → reactive recall → supply-chain disruption → billions lost → eroded trust.

The data exists. Nothing synthesizes it.

Device safety signals are scattered across six disconnected sources — the same n-tier visibility gap automotive and semiconductors are now racing to close. They stay trapped in silos until harm has already cascaded.



Regulatory databases

MAUDE, EUDAMED, recalls, Health Canada



Complaint hotlines

Clinician- and patient-reported issues



Hospital EHRs & outcomes

Usage patterns, unexpected complications



Manufacturer service logs

Factory tests, field service, RMA patterns



Claims data

Procedure codes, readmissions, revisions



Unstructured narratives

Clinical notes, forums, social signals

The missing piece is not more data. It is the same system-level capability every resilient supply chain needs — one that aggregates weak signals and closes the loop before harm cascades.

Three forces are forcing the industry to rebuild for resilience.

1



Regulatory

FDA's QMSR harmonizes U.S. device rules with ISO 13485, and EU MDR enforcement is tightening in parallel. Every manufacturer's postmarket workflow must be rebuilt — from periodic reporting to continuous surveillance.

2



Infrastructure

FDA's 2026 Adverse Event Monitoring System consolidates seven legacy databases into one real-time platform. The reporting fragmentation that blocked resilience layers for a decade is going away.

3



Demand

Value-based care means hospitals and payers must now demonstrate data-driven, safety-informed purchasing. Vendor claims are no longer enough — the buy-side wants real-world proof.

Today's systems are necessary but not sufficient: post-hoc, passive, fragmented. They document harm after the fact — none continuously synthesize signals into early action.

AI-native systems that reason across the safety ecosystem.

Not a workflow tool with AI bolted on — a system that fuses the silos and turns scattered weak signals into coordinated early action. Three capabilities make it work:



Domain knowledge graph

Fuses complaints, service logs, claims, EHRs and regulatory feeds so models reason on connected evidence — not isolated records.



Multi-step reasoning agents

Encode QMSR, EU MDR, IMDRF rules to distinguish a trend from a signal from a reportable event — across jurisdictions.



Human-in-the-loop assurance

Validated to ISO/TR 80002-2: every expert override is auditable and strengthens the model. Accountability stays human.



For manufacturers

Catch your own signals earlier. Stay compliant across regions, and innovate with confidence.



For hospitals & health systems

See across manufacturers — not one vendor's claims. Procure on evidence, and be first to know on recalls, not last.

AI doesn't just speed-up the supply chain. It changes what resilience means.



Efficiency and resilience stop competing

Long treated as a trade-off, AI's predictive analytics let firms optimize cost and absorb shocks at once.

Finance Research Letters, 2025



Resist with prediction, recover with learning

ML and predictive analytics pre-empt disruptors; reinforcement learning drives adaptive recovery in the crisis.

ICDECS, 2026



Generative AI sustains continuity under stress

A GenAI resilience framework held service above 90% and cut cost volatility ~20% across global disruption cycles.

Int. J. Production Research, 2025



AI's effect on resilience is nonlinear

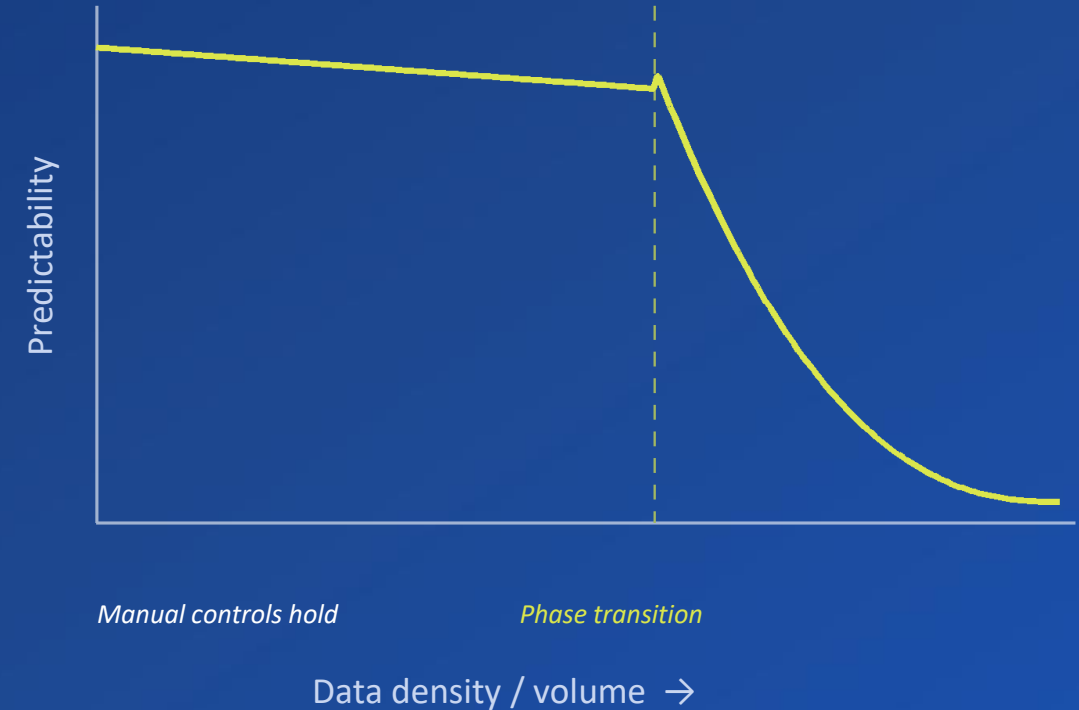
Threshold effects mean returns to AI jump once data infrastructure and adoption depth cross a critical point.

Scientific Reports (Nature), 2025

In complex adaptive systems, scale is rarely linear.

Beyond a threshold, systems undergo phase transitions. At low volume, human judgment reconciles weak signals and manual controls absorb noise. As data density rises, the signal-to-noise ratio deteriorates — and false confidence rises precisely when visibility is falling.

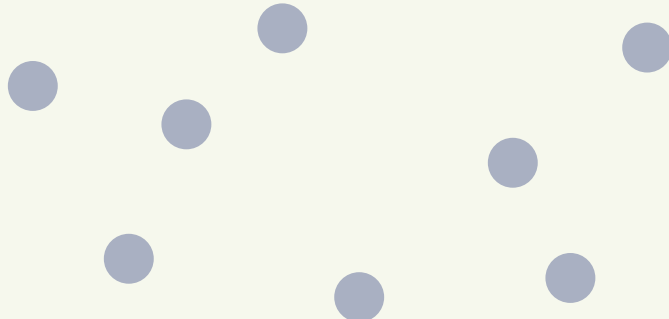
- Feedback loops tighten
- Coupling increases
- Predictability declines



In complex systems, aggregation is everything.

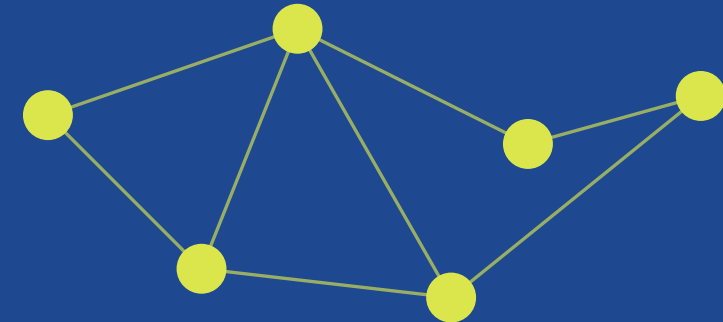
A weak signal only becomes visible when it is structurally connected. When information lives in disconnected spreadsheets, inboxes, and trackers, the signals never aggregate — and the anomaly stays buried in the variance.

SIGNALS SILOED



Disconnected. Each record closes on its own terms.

SIGNALS CONNECTED



Aggregated. The pattern emerges before harm cascades.

This is where compliance models quietly fail — not for lack of capability, but because the system was never designed for nonlinear scale.

A complaint isn't a task to close. It's a signal to read.

Complex systems don't fail all at once — they drift. Handle each complaint in isolation and three things happen:

01



Weak-signal detection dies

The earliest indicators of failure are soft — a slight rate shift, a cluster that shares a cause, not a category. Isolation kills the ability to see them.

02



Feedback loops break down

Resilient systems self-correct because information flows back through them. Processed as one-off tasks, the loop is severed — the system can't learn.

03



Drift becomes the baseline

Teams calibrate to a baseline that has already moved. What once would have been a flag becomes routine — until the pattern is an event, not an early warning.

Postmarket data can no longer live downstream.

Under QMSR and EU MDR, field evidence must inform risk, design, and benefit–risk — continuously, not annually. It has to flow back upstream.

01



Risk hides in the seams

The dangerous failures live in the handoffs — between complaints and design, PMS and clinical evaluation. Each function looks healthy alone.

02



Weak signals die in transit

Loosely coupled stages summarize and flatten a pattern on its way upstream. By the time it arrives, it has lost the texture that made it matter.

03



Decisions run on stale evidence

Benefit–risk shifts the moment a product meets the real world. Treating the original risk file as truth means deciding today with yesterday's data.

Resilient systems don't work harder under pressure. They are architected differently.



SENSE continuously

Detect weak signals where they emerge
— across complaints, field, and supply
nodes.



INTEGRATE across
boundaries

Connect the records so the pattern in
the relationships becomes visible.

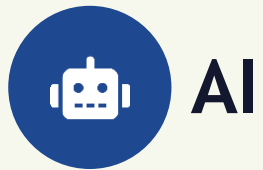


ADAPT before
instability compounds

Act on the signal in time — close the
loop while it is still an early warning.

Compliance, at scale, is a systems-design problem. Systems either evolve intentionally — or they transition unintentionally.

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



- Listens
- Connects
- Suggests
- Explains



- Decide
- Provide feedback
- Train the system



- Preserve the trace
- Maintain consistency

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

The resilient organization doesn't wait for a storm — or an inspector — to expose the seams.

It closes them now. Across every industry, the same capability separates the firms that absorb shocks from the ones that are absorbed by them:



Sense earlier

Convert weak signals into action while they are still cheap — days, not quarters.



Connect across silos

Aggregate fragmented evidence so the pattern is visible before harm cascades.



Adapt the network

Engineer redundancy and n-tier visibility so no single node can take the system down.

Connected Evidence isn't a quality investment. At scale, it is a commercial defense system.

The goal is not to automate responsibility.
The goal is to strengthen it.



Connect with me at

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