OMNITEK CONSULTING

Serialization Beyond the Minimum

WHITE PAPER

Turning a Compliance Requirement Into a Supply Chain Asset

Abstract

Most manufacturers built their serialization infrastructure to satisfy a specific regulatory deadline and have treated it as a compliance cost ever since. That framing misses what the data was always capable of doing. The World Health Organization estimates that at least 1 in 10 medicines in low- and middle-income countries are substandard or falsified, at an annual cost to health systems of roughly $30.5 billion, a problem serialized track-and-trace data exists specifically to help solve. Meanwhile, the average pharmaceutical recall costs between $10 million and $100 million, with the broader medical device industry facing up to $5 billion in annual recall-related costs. Every serial number a manufacturer generates to satisfy DSCSA or an equivalent global standard is also a data point that could sharpen recall targeting, verify supply chain integrity, and detect diversion, if the organization treats that data as an operational asset instead of an archival record kept only to satisfy an auditor. This white paper applies established data governance best practices to unlocking the value serialization data was always capable of producing.

The Compliance Box That Got Checked and Forgotten

Serialization arrived in most pharmaceutical organizations as a project with a hard deadline and a narrow objective: generate a unique serial number for every saleable unit, capture the required transaction data, and satisfy DSCSA or its international equivalents. Once that deadline passed, the infrastructure that generated and captured all that data typically settled into a quiet, unglamorous role. It ran in the background, fed the required reports, and got revisited mainly when an audit or an exception forced attention back onto it.

That framing treats a genuinely powerful dataset as a filing cabinet. Every unit-level serial number, every EPCIS event, every chain-of-custody record a manufacturer's system generates to satisfy a regulator is also a real-time signal about where product actually is, how it is actually moving, and whether the physical world matches what the paperwork says. Organizations that stop at the compliance minimum are sitting on operational value they never activate.

What Is Actually at Stake

The World Health Organization's data on substandard and falsified medical products makes clear how large the underlying problem is. At least 1 in 10 medicines in low- and middle-income countries are substandard or falsified, and countries collectively spend an estimated $30.5 billion per year contending with the consequences.[i] Serialization and track-and-trace infrastructure is one of the most direct tools available for detecting exactly this kind of product, since a falsified or diverted unit typically cannot produce a valid, chain-of-custody-consistent serial number history. A manufacturer using its serialization data only to satisfy a domestic reporting requirement is leaving that detection capability almost entirely unused.

Recall economics make the case just as directly. The average pharmaceutical recall costs somewhere between $10 million and $100 million, and the broader medical device industry absorbs up to $5 billion annually in recall-related costs, according to research cited by Honeywell's Sparta Systems.[ii] The single biggest lever for controlling that cost is precision: a recall that can identify the exact affected lots, serial ranges, and downstream locations moves faster and costs less than one that has to work backward from incomplete data. Serialized, unit-level data is precisely what makes that precision possible, but only if the organization has built the query and analysis capability to use it under time pressure, not just the capability to log it.

Why Most Organizations Stop at the Minimum

The reasons are structural, not a failure of imagination. Serialization programs are typically owned by regulatory affairs or quality functions whose mandate is compliance, not commercial or supply chain value creation, and the budget and success metrics for the program get set accordingly. Once the compliance deadline is met, there is rarely a mechanism that reopens the conversation about what else the infrastructure could do, because the team that built it has moved on to the next regulatory requirement.

There is also a genuine technical gap between logging data and being able to use it operationally. A system built to satisfy an auditor's request for historical records is not automatically built to answer an urgent operational question, such as which specific serial ranges from a suspect batch reached which specific distributors, in the

middle of an active recall. That capability requires deliberate investment in query performance, cross-system data integration, and analyst training that a pure compliance mandate never funds.

Applying Best Practices: From Compliance Record to Operational Asset

A core best practice in data governance holds that regulatory data infrastructure should be built once and reused across every purpose that data can serve, rather than rebuilt narrowly for each new requirement. Applied to serialization specifically, that means extending the same discipline into four capabilities that go beyond the compliance minimum.

1. **Recall Simulation Built Into the Data Model.** Build and regularly test the ability to answer a recall-scenario query, which specific units from a given lot or date range reached which specific downstream locations, before an actual recall forces that capability to be built under pressure.
2. **Diversion and Anomaly Detection as a Standing Function.** Serial numbers that appear in unexpected geographies, get scanned out of sequence, or show chain-of-custody gaps are signals worth actively monitoring, not just data worth retroactively reviewing after a complaint arrives.
3. **Cross-Functional Ownership Beyond Regulatory Affairs.** Give supply chain, commercial, and quality functions a genuine stake in the serialization data model, so the infrastructure gets funded and maintained as a shared operational asset rather than a single function's compliance line item.
4. **A Query Layer Built for Speed, Not Just Archival Completeness.** Invest specifically in the ability to answer urgent, specific operational questions quickly, since the value of serialization data during a live recall or investigation depends entirely on how fast it can be queried and trusted.

None of this requires re-serializing anything or replacing existing infrastructure. It requires treating the data that infrastructure already generates as an asset with uses beyond the report that originally justified building it.

What Going Beyond the Minimum Buys, and Where It Gets Hard

Advantages

- **Faster, more precise recalls:** the ability to identify exact affected serial ranges and their downstream locations directly shortens recall timelines and narrows their scope, reducing both cost and patient risk.
- **Earlier counterfeit and diversion detection:** standing anomaly monitoring catches suspicious patterns before they surface as a formal complaint or a regulatory inquiry.
- **Stronger commercial visibility:** supply chain and commercial teams gain real operational insight into product movement that a compliance-only mandate never funds them to access.
- **A stronger return on existing infrastructure:** the serialization system was already built and paid for. Extending its use multiplies the value of that investment rather than requiring a new one.

Risks and Barriers

- **Cross-functional funding friction:** shifting serialization from a single-function compliance cost to a shared operational asset requires budget and governance conversations that no single function currently owns.

- **Data quality gaps beneath the surface:** expanding use of the data can surface quality issues, missing scans, inconsistent formatting, that were invisible when the data was only used for basic compliance reporting.
- **Query performance limitations:** systems architected for periodic compliance reporting may not perform well under the speed and complexity demands of a live operational query, requiring targeted technical investment.
- **Organizational inertia:** a serialization program that has run quietly in the background for years faces natural resistance to being reopened as an active project, even for a clearly valuable purpose.

Case in Point: The Recall That Took Three Weeks Instead of Three Days

A mid-size generics manufacturer discovered a quality issue affecting a specific manufacturing run and needed to identify exactly which lots and serial ranges required recall. The underlying serialization data existed and was fully DSCSA-compliant, but the system had been built purely for periodic compliance reporting and had never been used to answer an urgent, specific operational query at speed. Extracting and cross-referencing the affected serial ranges against downstream shipment records took the compliance and IT teams working together nearly three weeks, most of which was spent building ad hoc queries the system had never been designed to support.

The recall itself, once properly scoped, was successfully contained to the correct lots. But the three-week delay in identifying that scope meant additional product shipped and reached distributors before the recall could be issued, expanding both the recall's ultimate size and its cost well beyond what a faster identification process would have produced. The manufacturer's subsequent investment in a dedicated recall simulation and query capability, built directly on the existing serialization data, reduced a comparable exercise in a later tabletop test to under three days.

Recommendations for Compliance and Supply Chain Leaders

1. **Run a recall simulation on your existing serialization data now.** before an actual recall forces you to discover whether the query capability exists under time pressure.
2. **Establish shared ownership of the serialization data model.** across regulatory affairs, quality, supply chain, and commercial functions rather than leaving it as a single function's compliance responsibility.
3. **Invest specifically in query speed and usability.** not just archival completeness, since operational value depends on how quickly and reliably the data can answer an urgent question.
4. **Build standing anomaly detection for diversion and counterfeit signals.** rather than only reviewing serialization data reactively after a complaint surfaces.
5. **Audit data quality proactively.** before expanding use of the data reveals gaps in a high-stakes, time-sensitive situation instead of a routine review.
6. **Reframe the serialization program's success metrics.** to include operational value delivered, not just compliance deadlines met, when justifying its ongoing budget.

Measuring Success: KPIs for Serialization Value Beyond Compliance

- **Recall simulation response time:** how quickly the organization can identify affected serial ranges and downstream locations in a tabletop recall exercise, tracked toward a target well under the timeline of an actual incident.
- **Anomaly detection coverage:** the percentage of serialized product flows actively monitored for diversion or counterfeit signals, rather than reviewed only retroactively.
- **Cross-functional data access:** the number of functions beyond regulatory affairs with active, regular use of serialization data for their own operational purposes.
- **Data quality completeness rate:** the percentage of serialization records passing a standing data quality audit, tracked as the foundation any expanded use depends on.

Conclusion

The infrastructure most manufacturers already built to satisfy DSCSA or an equivalent standard is capable of far more than the compliance report it was originally designed to produce. The scale of the problem that data can help address, a global substandard and falsified medicine market costing health systems an estimated $30.5 billion a year, and the cost of the failures better data access could prevent, pharmaceutical recalls running $10 million to $100 million on average, make the case for going beyond the minimum on their own.

Applying disciplined best practices to build a genuine operational asset means treating serialization data the way any other valuable dataset gets treated: with shared ownership, active monitoring, and investment in the ability to query it quickly when it matters most. Organizations that make that shift stop paying for compliance infrastructure that sits idle between audits and start getting a return on an investment they already made.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.

For compliance and supply chain leaders whose serialization program has quietly settled into a compliance-only role, OmniTek applies proven best practices to build a practical operational activation approach: recall simulation, standing anomaly detection, shared cross-functional ownership, and query capability built for speed. Whether you are looking to extract more value from infrastructure you already built or preparing your organization for a recall scenario you hope never happens, OmniTek can help you turn serialization from a line item into an asset.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.

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Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.

Endnotes

[i] World Health Organization, "Substandard and Falsified Medical Products," fact sheet, available at https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

[ii] Sparta Systems (Honeywell), "The Rising Cost of Product Recalls: Why Prevention Matters," citing McKinsey research on medical device recall costs, available at https://www.spartasystems.com/resources/the-rising-cost-of-product-recalls-why-prevention-matters/