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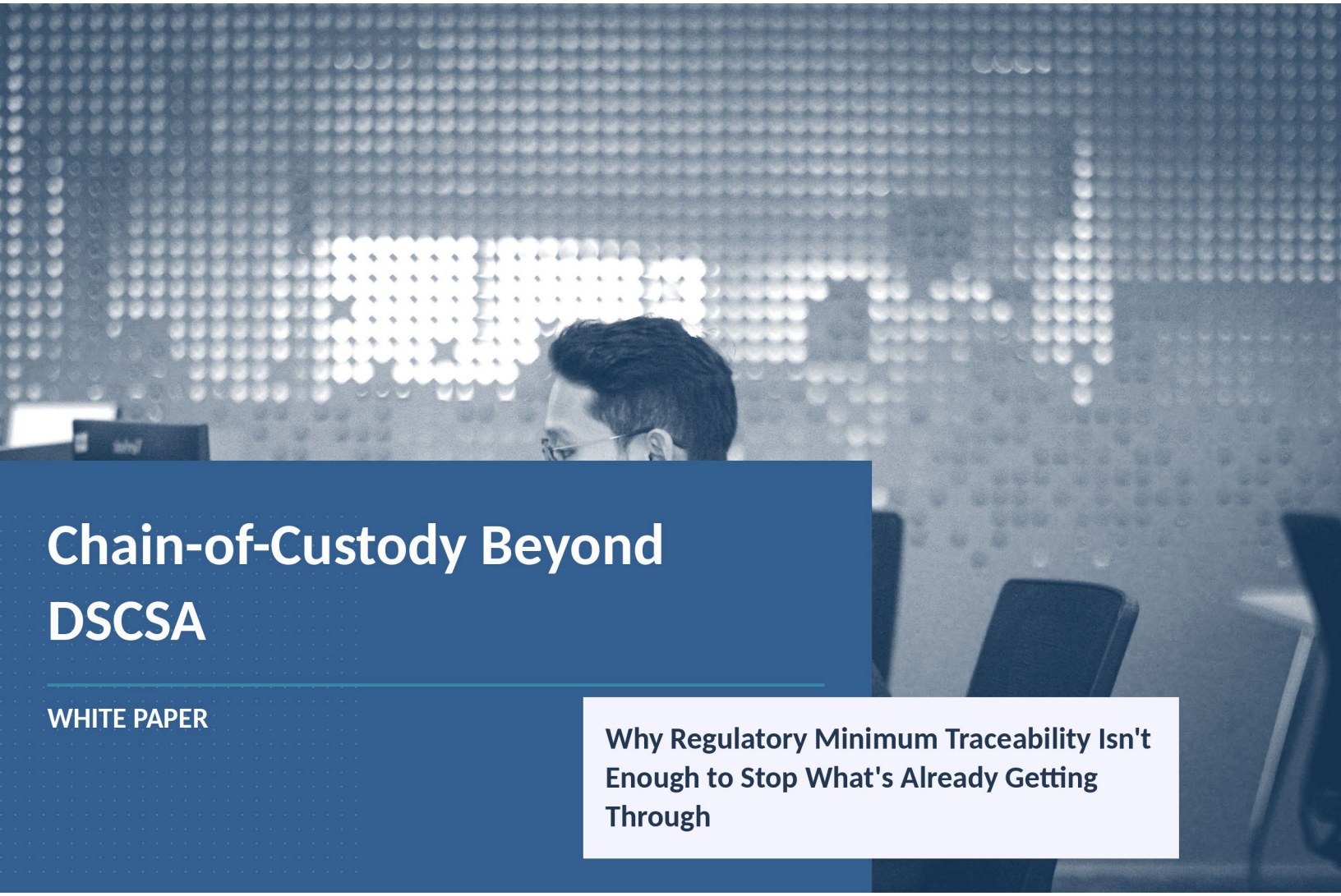

Chain-of-Custody Beyond DSCSA

WHITE PAPER

Why Regulatory Minimum Traceability Isn't Enough to Stop What's Already Getting Through

Abstract

DSCSA compliance proves that a product's serialized identifier moved correctly through authorized trading partners. It does not, by itself, stop a diverted product repackaged with the wrong contents from reaching a patient, or a counterfeit product carrying a valid-looking serial number from clearing a scan. Real incidents keep illustrating the gap: counterfeit injectable products distributed with nonsterile needles, and diverted medications repackaged with foreign objects in place of the actual drug, both cases where the packaging and documentation looked compliant on the surface. Globally, countries lose an estimated $30.5 billion a year to substandard and falsified medical products, a cost that regulatory serialization requirements alone have not eliminated. This white paper applies established supply chain reconciliation best practices beyond DSCSA's regulatory floor, laying out a chain-of-custody practice built to catch the diversion and counterfeiting patterns that a compliant scan does not, by itself, reveal.

What DSCSA Compliance Actually Proves, and What It Doesn't

The Drug Supply Chain Security Act was built around four core pillars: verifying that trading partners hold proper state licensure and FDA registration, tracking serialized data at the individual unit level with six-year retention, following defined protocols for investigating suspect or illegitimate product, and maintaining written operational policies. Meeting these requirements, especially as the final compliance deadlines for smaller pharmacies close out through November 2026, is a substantial undertaking, and organizations that have completed it have real traceability infrastructure in place.

What DSCSA compliance proves is that a serialized identifier moved through a documented chain of authorized trading partners. It does not, on its own, guarantee that what is inside the package matches what the serial number claims, or that a product carrying a valid-looking code has not been tampered with, diverted, or counterfeited somewhere the documentation does not capture.

Real cases make the gap concrete. Counterfeit semaglutide products have circulated with nonsterile needles inside otherwise convincing packaging. Diverted medications, including HIV treatments, have been documented repackaged with foreign objects, rocks, in place of the actual product, while retaining outward packaging that passed a casual inspection.[i] Neither case was caught by the serialized identifier alone. Both required the kind of vigilance that goes beyond scanning a barcode and confirming it resolves.

Why the Regulatory Floor Was Never Meant to Be the Ceiling

DSCSA was designed to close a specific set of gaps: paper-based pedigree systems that were easy to falsify, and a lack of standardized data to support supply chain investigations. It succeeded at that. It was never designed to independently verify the physical contents of every package or to catch every diversion scheme a sophisticated bad actor could construct.

Countries lose an estimated $30.5 billion a year to substandard and falsified medical products, a figure that has persisted even as serialization requirements have expanded across major markets.[ii] That persistence is the clearest evidence that regulatory minimum traceability, while necessary, is not sufficient on its own. The organizations that stay ahead of diversion and counterfeiting risk are the ones treating DSCSA compliance as a floor to build on, not a finish line.

Industry tools are starting to reflect this. The National Association of Boards of Pharmacy's Pulse platform, for instance, lets a pharmacist scan a barcode and instantly verify a serial number's validity directly with the manufacturer, extending verification beyond what a static, compliance-only workflow would catch on its own.

Applying Best Practices: A Chain-of-Custody Practice Beyond the Regulatory Floor

A foundational best practice, reconciling data across a fragmented set of sources into one trustworthy record, applies directly to the gap between DSCSA-compliant documentation and physical product integrity. Applying it as a full chain-of-custody practice means building verification layers that do not stop at a valid serial number.

1. **Physical and Digital Verification, Not Digital Alone.** Pair serialized data verification with physical inspection protocols and red-flag training, so a valid-looking scan is not treated as sufficient confirmation on its own.

2. **Trading Partner Behavior Monitoring.** Track ordering patterns, shipment origins, and transaction anomalies across the trading partner network, not just credential validity, to catch diversion patterns that look compliant on paper.
3. **A Standing Suspect Product Investigation Discipline.** Build the DSCSA-required investigation protocol into a continuously staffed function rather than a rarely exercised procedure, so unusual patterns get investigated in real time.
4. **Direct Manufacturer Verification Integration.** Connect dispensing and distribution points to real-time manufacturer verification tools, extending confirmation beyond what static transaction records alone can provide.

None of this requires abandoning DSCSA's serialization infrastructure. It requires building the reconciliation and anomaly-detection layer already applied to other compliance data, extended to catch the specific patterns, unusual sourcing, physical inconsistencies, behavioral anomalies, that a compliant-looking transaction record does not surface on its own.

What Extended Chain-of-Custody Buys, and Where It Gets Hard

Advantages

- **Catches what serialization alone misses:** physical inspection and behavioral monitoring address the counterfeiting and diversion patterns that a valid scan does not by itself reveal.
- **Faster response to emerging threats:** real-time manufacturer verification and trading partner monitoring shorten the time between an anomaly appearing and it being caught.
- **Stronger defense in an FDA inspection:** a documented, active investigation discipline demonstrates more than paper compliance with DSCSA's suspect product provisions.
- **Reduced patient safety exposure:** closing the gap between compliant documentation and physical product integrity directly reduces the risk of a diverted or counterfeit product reaching a patient.

Risks and Barriers

- **Physical inspection does not scale like scanning does:** adding meaningful physical verification steps requires staff time and training that a pure barcode workflow does not.
- **Behavioral monitoring requires a real baseline:** detecting an anomaly in trading partner behavior requires first knowing what normal ordering and shipment patterns look like, which takes time to establish.
- **Smaller organizations face resource constraints:** the smallest pharmacies and distributors, the same ones just reaching DSCSA's final compliance deadlines, often have the least capacity to build additional verification layers.
- **Sophisticated counterfeiting keeps adapting:** no verification layer is permanent protection against actors who study and adapt to whatever detection method is currently in place.

Case in Point: The Reorder Pattern That Didn't Match the Region

A mid-size specialty distributor's compliance team had fully implemented DSCSA's serialized verification requirements and had never failed a scan-based check. During a routine review of trading partner activity, an analyst noticed that a licensed pharmacy customer in a low-population rural region had placed reorders for a high-value injectable product at a volume more consistent with a mid-size urban clinic network.

Every individual transaction had passed serialized verification. Every trading partner credential was valid. Nothing in the DSCSA-required documentation flagged the pattern, because DSCSA's verification requirements were never designed to evaluate whether an order volume made sense for a given customer's actual patient population. The distributor's investigation, prompted entirely by the behavioral anomaly rather than any compliance failure, ultimately traced the pattern to a diversion scheme routing product through the pharmacy toward an unauthorized secondary market.

The distributor's serialized data had been completely compliant throughout. What caught the problem was a chain-of-custody practice built on top of that compliance, one that treated order pattern monitoring as a standing discipline rather than an occasional audit exercise.

Recommendations for Supply Chain and Security Leaders

1. **Treat DSCSA compliance as the floor, not the finish line.** and build a chain-of-custody roadmap for what comes after serialization is fully implemented.
2. **Add physical inspection protocols alongside digital verification.** with staff trained on the specific red flags that have appeared in real counterfeiting and diversion cases.
3. **Build a trading partner behavior baseline.** so unusual ordering, shipment, or transaction patterns can be identified against a known normal rather than caught only by chance.
4. **Staff the suspect product investigation function continuously.** rather than treating it as a rarely used procedure that exists only on paper.
5. **Adopt direct manufacturer verification tools where available.** to extend confirmation beyond what static transaction records can provide on their own.
6. **Share anomaly patterns across the trading partner network.** since diversion schemes often touch multiple organizations before detection, and early information sharing shortens that window.

Measuring Success: KPIs for Extended Chain-of-Custody

- **Behavioral anomaly detection rate:** the number of trading partner pattern anomalies identified through active monitoring versus those discovered incidentally, tracked toward proactive detection.
- **Suspect product investigation cycle time:** how long it takes from an anomaly being flagged to a completed investigation, tracked toward faster resolution.
- **Physical verification coverage:** the percentage of high-risk product categories with an active physical inspection protocol beyond serialized scanning.
- **Direct manufacturer verification adoption:** the percentage of dispensing and distribution points connected to real-time manufacturer verification tools.

Conclusion

DSCSA compliance is real infrastructure, and organizations that have built it should not discount that work. But a valid serialized identifier proves a product moved through documented, authorized hands. It does not prove what is inside the package, and it does not catch a diversion scheme built to look compliant on paper while routing product somewhere it was never meant to go.

Applying disciplined best practices to a full chain-of-custody practice, physical verification alongside digital, behavioral monitoring alongside credential checks, a continuously staffed investigation function rather than a dormant procedure, closes the gap between regulatory compliance and actual supply chain integrity. At $30.5 billion a year in global losses to substandard and falsified products, that gap is not closing on its own.

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 supply chain and security leaders looking past DSCSA's regulatory floor, OmniTek applies proven best practices to build a practical chain-of-custody practice: physical and digital verification working together, trading partner behavior monitoring, and a standing suspect product investigation discipline. Whether you are finishing your DSCSA implementation or building the next layer of defense against diversion and counterfeiting, OmniTek can help you build a supply chain integrity program that goes beyond what the regulation alone requires.

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

McLean, VA | Serving clients nationwide
info@omnitekconsulting.com
omnitekconsulting.com

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

Endnotes

[i] Drug Topics, "Securing the Supply Chain Through Interoperability and Vigilance," on DSCSA compliance pillars, the NABP Pulse verification platform, and documented counterfeit and diversion incidents, available at https://www.drugtopics.com/view/securing-the-supply-chain-through-interoperability-and-vigilance

[ii] World Health Organization, "Substandard and Falsified Medical Products," fact sheet citing an estimated $30.5 billion in annual global losses, available at https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products