Four Ways to Ensure Continuous Compliance with Global Track-and-Trace Regulations



Pharmaceutical manufacturers worldwide are grappling with a growing number of complex serialization and track-and-trace compliance requirements. These regulatory requirements change frequently, even after they go into effect, which makes it difficult to manage the scope of change. Yet the consequences of non-compliance are severe and far reaching, impacting your ability to meet contracts and generate revenue, fulfill your partner relationships, and potentially ensure on-time delivery of critical products to patients.

TraceLink offers a proven global compliance platform designed to help customers achieve continuous compliance and run their compliance initiatives with confidence. From our extensive **TraceLink Community**, which includes industry professionals from more than 1,600 global companies spanning the end-to-end global pharmaceutical supply chain, to flexible compliance solutions designed to help organizations meet requirements in more than 20 regions, TraceLink strives to provide our customers with everything they need to stay informed and in line with compliance requirements.

This article explores why keeping up with these mandates can be so difficult and how TraceLink helps you stay ahead of regulatory requirements with a variety of

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resources and technical solutions. When you're done reading the article, be sure to **visit this page to join the TraceLink Community** and begin networking with your peers.

The challenge of keeping up with global compliance mandates

The way regulatory requirements are communicated at a global scale varies widely across regions, as do the requirements themselves. For example, directives vary on whether product movement should be reported to a centralized system or directly to a trading partner, how decommissioning at the point of dispense should be handled, how suspect product verification should be managed, and much more. As a result, managing requirements can be time consuming, both in terms of understanding the specifics of the requirements and the timing of enforcement.

Further exacerbating this challenge is the hurdle of compliance deadlines, which are often set before the actual regulations are established. For example, the U.S. Drug Supply Chain Security Act (DSCSA) has 2023 requirements for product tracing, but the industry has not agreed how this should be done.

How TraceLink helps you achieve compliance with global mandates

The complexity of global mandates can be overwhelming. This is where TraceLink can help. For more than a decade, TraceLink has played an active role in developing and shaping global compliance standards, working with organizations like GS1 to provide playbooks describing what manufacturers, wholesalers, and dispensers need to do to comply with federal traceability frameworks like DSCSA. With more than 290,000 member organizations on our pharmaceutical industry network platform, TraceLink also delivers deep insight into the needs of organizations across the supply chain.

With this wealth of experience, we understand the intricacies of local regulations and the need to be agile to keep up with ever-changing mandates. Based on our experience working with pharmaceutical manufacturers, distributors, contract

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manufacturers, 3PLs, dispensers, and healthcare organizations on compliance matters, there are four best practices companies that companies should adopt if they want to stay on top of mandates:

1. **Become an active participant in industry forums**, like the TraceLink Community groups. With regular networking meetings and expert support, over 6,400 community members across 1,600 global companies share best practices and insights on evolving global requirements. The community model allows participants to learn from their peers, many of which have experience navigating regional compliance requirements and establishing their own best practices for maintaining compliance.

2. **Nominate a point person or establish a center of excellence** to standardize the approach to compliance, ideally with input and participation from both business and IT stakeholders. Many companies are currently unprepared to meet the challenges built into the final stage of the DSCSA simply because traceability and compliance is often not the central focus of any one person's job. This is another area where the TraceLink Community helps by enabling participants to gain insight into compliance best practices so they can accelerate their knowledge and lead their organizations through the compliance journey.

3. **Work with a trusted advisor and industry expert.** TraceLink is actively involved in the standards definition and alignment process, which can help ease the burden of compliance. TraceLink strongly supports the creation and development of global interoperability standards, and our solutions reflect that experience. TraceLink is also strongly committed to educating the industry and customers, regularly delivering thought leadership on the latest compliance topics over the last decade. Most recently, **we held a 4-month educational series on DSCSA 2023**, which was attended by more than 2,900 industry professionals.

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4. **Treat compliance as an ongoing process**, rather than a one-time project. Any traceability and compliance implementation should be accompanied by change management techniques to ensure continuous compliance. TraceLink has demonstrated a commitment to supporting compliance with new country regulations as they emerge and we've designed our compliance solutions with an architecture that can rapidly deploy updates while maintaining existing partner integrations and a validated state. TraceLink provides more than 20 regional regulatory compliance solutions that ensure continuous compliance with track-and-trace requirements, covering mandates from the United States, European Union, Saudi Arabia, Russia, Bahrain, and more. To date, more than 730 companies are using two or more of the regional compliance solutions, which reduces compliance risk and costs.

Get involved with the TraceLink Community!

TraceLink works continuously with our customers, network members, partners, and government regulatory agencies to understand new requirements and specifications. We regularly share and discuss these insights with the TraceLink Community. For more information, please **visit the Community hub for a list of active groups and topics**. You can also sign up to take part in the TraceLink Community conversations by **updating your TraceLink communication preferences**.

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Contact TraceLink to learn more about our compliance solutions!
Fill out the form to contact us now.

Thank you for contacting us; we'll be in touch shortly.

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