As DSCSA Manufacturer Serialization Enforcement Begins, More Than 250 TraceLink Customers Are Live



Today marks the end of the FDA's enforcement discretion period for manufacturers subject to serialization regulations under DSCSA.* As full enforcement gets underway, TraceLink congratulates the more than 250 U.S. manufacturers it has helped go live with serialization as they achieve this significant milestone.

Industry readiness for serialization

At the November 2018 FutureLink conference in Chicago, pharmaceutical industry executives were polled on their business and operational readiness as serialization enforcement begins. A resounding 86% reported that they were compliant and ready to meet the November 2018 milestone, though some were relying on grandfathered product and other tradeoffs to have accomplished this. Just 14% expressed concern about their ability to be fully compliant at this time.

2019: Focusing on saleable returns and serialized operations

The same executives at FutureLink indicated that meeting the November 2019 DSCSA Saleable Returns Verification requirement will be a priority next year. Nearly three-quarters reported that using a Verification Router Service (VRS) is their preferred approach for connecting to manufacturer and distributor partners, and two-thirds of those surveyed are already actively researching, piloting, or

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testing solution options.

TraceLink: a platform for compliance and growth

Nearly half of those surveyed—46%—are already planning to optimize their digital infrastructure and explore ways to realize new business opportunities. For TraceLink customers, the connectivity of the industry's only information-sharing network gives them the ability to integrate once and interoperate with everyone to meet 2019 requirements, adapt to evolving regulations, and take advantage of emerging business opportunities in the U.S., the EU, and around the world. To date, more than 650 global manufacturers have chosen TraceLink as their solution provider.

For companies with upcoming DSCSA saleable returns requirements, TraceLink's Product Information Manager is the only solution that combines robust VRS performance with master data sharing for uninterrupted business efficiency. With out-of-the-box partner connectivity and technology based on open, interoperable standards, Product Information Manager ensures that companies can comply with FDA regulations, meet new trade partner requirements, and be prepared for all-digital traceability in 2023. Learn more about TraceLink's Product Information Manager.

**While the law mandated that all eligible products packaged after November 2017 must be serialized, many companies used the FDA's stated 12 month enforcement delay to finalize their preparations.*

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

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TraceLink Announces Availability of End-to-End DSCSA Saleable Returns Verification Solution for Pharmaceutical Manufacturers and Wholesale Distributors

TraceLink announced availability of its end-to-end saleable returns verification solution for pharmaceutical manufacturers and wholesale distributors, including a verification router service (VRS) and master data sharing capabilities built on its new Product Information Manager network application, as well as Edge functionality for processing saleable returns.
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