RESOURCES

Is Your ERP System Really "Serialization-Ready?"

A common response from wholesalers who are using their ERP systems for lot-level DSCSA compliance is to say, "My ERP can handle serialization." The fact is: ERPs are the right tool for managing business operations, but are not designed to handle the serialization and compliance operations necessary for meeting DSCSA regulations. Beginning in November 2019, wholesalers must verify that they are receiving and selling only serialized products and must re-verify all 4 data elements of every returned product's unique identifier before it can be resold: Global Trade Item Number (GTIN), lot number, expiry date, and serial number.

The ability of newer ERP systems to manage 2019 DSCSA requirements is uncertain or unproven—if it's even on their product roadmaps. And, because most legacy ERP systems are already highly customized, adding additional customization to handle serialization performance requirements—at scale—exposes your critical business systems to significant risk of failure. Before you turn to your ERP to handle DSCSA compliance and serialization, ask these important questions:

How much does my ERP provider really know about complying with FDA regulations?

How much are you paying your ERP provider or system integrator to "come up to speed" on FDA and DSCSA requirements? ERP providers typically have limited

resources dedicated to understanding evolving DSCSA regulations—compared with a solution provider focused on track-and-trace solutions that can help you navigate the full spectrum of compliance challenges and understand what you need to respond to an FDA inquiry.

What's the best way to minimize the impact of saleable returns verification?

The 2019 DSCSA Saleable Returns Verification requirement will have a significant operational impact on manufacturers and wholesalers. To ensure that saleable returns don't slow down pick/pack/ship operations, the industry is moving toward using a verification router service (VRS) model that can send a verification request to a manufacturer and receive a response in near real-time.

As an alternative, manufacturers can send standard EPCIS* serialization data with each shipment to be stored by the wholesaler to "self-verify" a saleable return—but because manufacturers are not required to provide EPCIS data until 2023, wholesalers that are planning to self-verify returns are realizing the need for a VRS when EPCIS data is not available.

In either scenario, legacy ERP systems would require extensive customization to handle the complexity of determining if a serial number can be self-verified or must be routed through a VRS. To date, only the largest ERP providers are actively exploring VRS interoperability.

Will my ERP be overwhelmed by serialization data?

Unlike lot-level tracking—where only a single batch number is applied to hundreds or thousands of units—serialization requires that every salable unit has its own unique identification number. While some ERP systems offer basic lot-level compliance features, unit-level serialization represents a quantum leap over lot-level compliance in terms of complexity and data storage.

For companies that are planning to create their own serial number repositories to

self-verify saleable returns, the enormous volume of unit-level serial numbers and associated EPCIS event data will add up fast. A traditional ERP system will soon reach its data and performance limits—and slow down critical business operations.

How much will customizing my ERP really cost?

Adapting an ERP system to handle serialization is a short-term solution with long-term downside. If you are customizing a legacy ERP system, you will continue to pay for software updates to meet evolving regulations and manage individual point-to-point connections with multiple suppliers. And even newer ERP solutions don’t offer the proven functionality and seamless upgrades of a purpose-built serialization solution built on a cloud-based platform.

Will my ERP prepare me for 2023 DSCSA requirements?

The DSCSA requirements do not end in 2019—and neither does the cost or complexity of customizing your ERP system. By 2023, when all-electronic traceability at the unit level will be required, wholesalers will need systems that can share and manage digital transaction information, and ERP systems are not designed to handle large volumes of transactional data using the multi-layer EPCIS data model.

Scalability and connectivity: the TraceLink advantage

The key to a successful, long-term compliance and serialization strategy—and lower cost of ownership—is choosing a solution that can scale easily to meet growing data requirements and provide fast, secure data connectivity.

TraceLink is the only purpose-built solution that offers:

- A data architecture that allows nearly unlimited scalability.
- A trusted, secure network-based model for connecting with all partners.
- Applications based on open, interoperable industry standards.
- Synchronized upgrades and automated validation for seamless compliance.
- User interfaces designed for compliance workflows and serialized operations.

Only TraceLink offers the connectivity of its information-sharing network and the flexibility of a native, cloud-based platform to eliminate the need for custom workarounds and constant short-term fixes. The TraceLink platform provides the right level of out-of-the box functionality to meet your 2019 requirements, prepare you for 2023, and protect your ERP investment by separating compliance and serialization operations from business-critical operations—allowing your ERP to function as designed.

* *EPCIS (Electronic Product Code Information Services) is a global GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.*

United States

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