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5 Risk Factors of Using Your LMS Provider to Meet Brazil Compliance Requirements



Line Management System (LMS) vendors have an important role in the physical implementation of product serialization because they write the software drivers and controllers for the vision and printing hardware on the packaging line. However, LMS providers offer limited, point-to-point integration capabilities that simply cannot scale to meet the data management, connectivity, and system performance demands of a market as vast and diverse as Brazil. Enterprise-level data exchange between manufacturers and their partners will be essential to prevent shipping delays and product shortages due to Brazil's especially challenging compliance choreography.

Enterprise-level software requires a deep set of workflow capabilities and a network platform capable of handling diverse partner data requirements to ensure accurate and timely compliance reporting. This represents unfamiliar territory for LMS vendors—and a significant risk for manufacturers that choose to rely on a solution provider without the proven software and integration services to meet their enterprise-level serialization needs.

What is Enterprise-Level Serialization?

Serialization impacts multiple aspects of a company's supply chain infrastructure, from packaging lines to data exchange with your business systems, CMOs,

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downstream partners, and regulatory systems. A five-level model can be used to understand the interlocking components of serialization and reporting—with each layer performing a distinct function and communicating the serialization information up to the next level.



LMS vendors work at the device, packaging, and site serialization levels (L1 – L3) focusing on the hardware, automation, and control solutions that manage the printing and inspection of serial numbers and product aggregation. Their expertise is in vision systems, image detection, and mechanical design. Since serial numbers must be printed and inspected, managing the physical application of serialization is a natural extension of their core capabilities. Enterprise-level serialization enables complex serialized operations and customizable workflows as well as seamless data exchange across both internal systems and a network of partners and government authorities. To enable the exchange of data between MAHs and their CMOs and 3PLs, Level 4 – 5 solution providers must provide uninterrupted connectivity between manufacturing and logistics partners' systems with software solutions architected to seamlessly manage ongoing change.

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Side-by-Side Comparison: LMS vendors and TraceLink

TraceLink offers a purpose-built software solution that provides Level 4 – 5 capabilities to Life Sciences supply chain companies so they can meet the requirements of serialization regulations around the world. TraceLink integrates with the industry's most popular line systems manufacturers, and can partner with your LMS vendor to provide seamless Level 4 – 5 functionality.

Evolving regulations and business requirements mean frequent software changes. In addition, more than half of the top Marketing Authorization Holders (MAHs) require custom interfaces, and Contract Manufacturing Organizations (CMOs) are often asked to develop custom plug-ins to handle unique business rules for clients. TraceLink continuously monitors changes to Brazil regulations as well as trade partner requirements; works with industry and customers to understand their business impact; implements the required changes; and quickly releases updates to keep its customers in compliance. And, once changes are deployed, TraceLink automated validation tools ensure that their software meets industry standards.

Required Capability: Software Expertise

LMS vendors: LMS vendors specialize in hardware automation, control software, and other "closed systems." They are not accustomed to the software development lifecycles, support processes, and service elements of an enterprise-level software solution. As a result, LMS vendors do not have the processes or architecture necessary to sustain frequent updates required by an evolving regulatory landscape such as Brazil.

TraceLink: TraceLink has been a pioneer in distributed software applications for the Life Sciences industry since 2003 and our digital supply network connects more than 281,000 partners across the global pharmaceutical supply chain. TraceLink's multi-tenant application architecture is designed for continuous change, backed by a rigorous set of standard operating procedures that govern product development, quality assurance, software compliance, and ongoing

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support services.

Required Capability: Ensuring Enterprise-Level Business Continuity

LMS vendors: An LMS vendor that is proposing an enterprise-level serialization solution will need to satisfy a set of baseline requirements to ensure business continuity even as software is continually updated, including system uptime guarantees, prevention of data loss, system performance management, audit trails, and 24/7 support.

TraceLink: Over 900 manufacturing and packaging companies rely on TraceLink serialization and compliance solutions to meet miss their benchmarks for uninterrupted business operations:

- Uptime: TraceLink guarantees 99.95% uptime, as required for mission-critical applications.
- Hardware redundancy: TraceLink's active-active architecture, which dictates that data resides in two different physical locations, ensures no data loss in the event of a hardware failure.
- Performance issues and security failures: TraceLink continuously monitors its systems and resolves any issues, removing the burden from our customers.
- Audit trail: TraceLink solutions are customized to meet country-specific compliance and validation requirements, including audit trails.
- 24/7 support: TraceLink's services organization comprises more than 100 service professionals, dedicated to providing support in 15 languages—around the clock and around the globe.

Required Capability: Adapting to Changing Requirements

LMS vendors: LMS vendors are accustomed to an environment where line systems are closed off from external disruptions, where software is installed once and only infrequently updated—usually involving long development and testing cycles. And because LMS systems are typically on-premise and single-tenant solutions, upgrades and re-validation processes are time- and budget-intensive.

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TraceLink: TraceLink provides compliance-as-a-service, with teams dedicated to monitoring and quickly implementing regulatory changes through a multi-tenant network architecture designed to distribute updates to customers as soon as they are available. For software validation, TraceLink executes the Installation and Operational Qualifications (IQ and OQ), and provides support for the final Performance Qualification (PQ). All of this is included as part of our customers' regular subscriptions, and we offer additional services for automating the entire validation process.

Required Capability: Vertical and Horizontal Integration

LMS vendors: In addition to "vertical" integration with the government's central reporting system, "horizontal" data exchange with direct and indirect partners will be a critical business requirement to ensure compliance and business continuity in Brazil's multi-enterprise pharmaceutical supply chain. Most LMS vendors handle partner integrations on an individual point-to-point basis, using the Open Serialization Communication Standard which was developed to exchange data between packaging and site level systems—not to send data to government and trade partner systems.

TraceLink: The TraceLink network, which connects more than 281,000 Life Sciences supply chain partners, allows companies to Integrate Once, Interoperate with Everyone™, minimizing the cost, time, and risk of connecting with partners. If any of your partners are not already on the TraceLink network, TraceLink's dedicated Network Success Team takes care of the on-boarding of new partners. TraceLink's serialization solution also uses configurable workflows to solve for all the diverse data requirements and reporting workflows that your partners may have. For example, if a trade partner imposes a size limit on data files, or requires a naming convention with custom data parameters, TraceLink will manage that for you.

Required Capability: Serialization Workflow Management

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LMS vendors: Because LMS providers do not offer Level 4 software capabilities or the pre-built business logic designed to track and manage events associated with serialized products as they move through supply chain and distribution processes, companies must embed serialization event management software into their ERP and WMS systems, a costly and time-consuming integration project.

TraceLink: TraceLink's purpose-built serialization solutions and customizable workflows provide proven serialized operations management capabilities so that serialized supply chain and distribution processes do not need to be integrated into ERP and WMS systems. TraceLink's Serialized Operation Manager allows company to:

- Track and manage serialized product post-packaging.
- Manage aggregation and disaggregation processes.
- Monitor the current state and history of serialized inventory.
- Execute supply chain transactions such as receipts, transfers, and shipments of serialized product.
- Execute business logic based on event data and master data.
- Integrate an edge device layer to enable serialized operations on the warehouse floor.

In addition, TraceLink's independent EPCIS (Electronic Product Code Information Services) repository allows companies to scale quickly to meet the processing and storage demands required by serialized operations

Case Study: Level 4 and 5 Capabilities Prompts Pharma to Switch to TraceLink

For a large European pharma company selling a high volume of medicines covered by the EU Falsified Medicines Directive (FMD), finding a solution to exchange serialization data with more than 100 CMOs by the FMD deadline was critical for business continuity. When the company realized that the original provider's plan to build and test point-to-point connections to all of them from scratch was not viable,

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they turned to TraceLink for its proven Level 4 enterprise-level distributed software and Level 5 network connectivity. TraceLink offered:

A proven serialization solution to achieve compliance quickly. As a leading level 4 – 5 solution provider, TraceLink offered a proven serialization playbook and a purpose-built EU FMD compliance module that could be quickly integrated with the company's systems.

A network model for swift partner onboarding. With the TraceLink Life Sciences Cloud, all the company needed was one connection to TraceLink to exchange data with all of their CMOs and pharma customers, as opposed to developing over 100 point-to-point connections.

Dedicated, expert teams for smooth implementation. TraceLink's locally based implementation and services teams provided native-language support to onboard the company's partners and ensure business continuity.

TraceLink: A Proven Solution to Eliminate Risk

With a tight timeframe until the 2022 ANVISA deadline takes effect in Brazil, there is no time to start over if you choose a partner that does not have the local expertise—and proven solution—to enable your success. TraceLink streamlines track and trace compliance with a proven, purpose-built software serialization solution that has been selected by more than 900 manufacturers and distributors in order to comply with regulations in Europe, the United States, Russia, China, India, and South Korea.

Only TraceLink offers solutions and services that leverage your serialization investment to create new business value. From automated software validation and expert training to enterprise-wide exception management with TraceLink's Serialized Product Intelligence application, TraceLink lets you transform local compliance operations into a center of operational excellence.

Brazil Pharmaceuticals<a

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href="/region-type/brazil" hreflang="en">Brazil
Learn more about TraceLink's Brazil Compliance solution.
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Thank you for contacting us; we'll be in touch shortly.

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