

RESOURCES

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# The 5 Levels of Serialization and Information Management



As you begin to tackle regulatory compliance, you'll hear references to the different "levels" of serialization. Each "level" is a stage of the serialization process, primarily focused on information management and exchange. If you lack any of the components at each level, you put your business at risk of costly and time-consuming mistakes in the field.

While the packaging-related issues receive most of the focus, it's important to start at the highest level of serialization and information management. Here's what each level represents:

#### Level 5 - Network

A global network enables management of all serialization and regulatory data with partners, customers, and regulatory authorities. Provided by a serialization solution vendor with a global supply chain network.

## **Level 4 - Enterprise**

A global enterprise system enables management of all serialization and regulatory data and business processes. Provided by a serialization solution vendor, an L4 is necessary to manage and verify the data that must accompany each serial number. When you begin serialization on the packaging line (L1-L3), you must at the same time determine how you will use and integrate the lines with your



enterprise architecture (L4).

#### Level 3 - Site-level serialization

Software that allocates serial numbers to lines, verifies the integrity of information submitted to the enterprise system and performs changes to aggregation hierarchies and processing of shipments. Traditionally provided by individual line management system (LMS) vendors to work with their specific equipment, but LMS-agnostic site servers that can work with different line systems are beginning to emerge.

### **Level 2 - Packaging pick/pack**

Line software that maps with your L1 to manage hardware and printing systems in conjunction with your packaging line. L2 software manages devices that serialize and pack product and supports device integration with site systems for conducting warehouse operations. Provided by LMS vendors.

#### Level 1 - Device

This includes hardware devices such as cameras, printers, and vision inspection equipment that perform printing, vision inspection, rejection, and materials-handling on the line. Provided by LMS vendors.

At every level of serialization, leveraging interconnectivity and interoperability is vitally important—the decisions you make today can impact the operational performance of trade partners, suppliers, government agencies, and customers. That's important to keep top of mind when deciding on systems best-suited for your business.

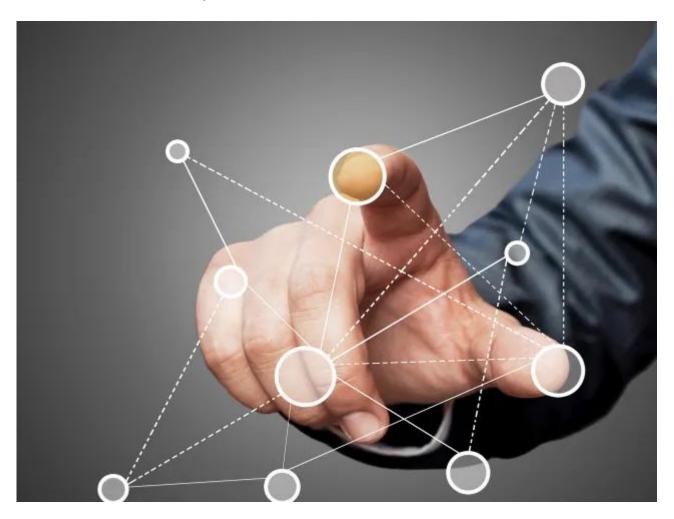
To gain a deeper understanding of the basics of serialization, download our Serialization: Where to Begin eBook.

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#### **More Serialization and Compliance Resources**



Planning for Serialization: A Top-Down Approach

Serialization challenges make it critical to start strategizing from the network down to the device level. Watch this to prepare your IT operations.





Four Reasons Why Pharma Companies Need a Serialization Intelligence Solution

Pharmaceutical companies need real-time visibility into operations, people, and systems across serialization infrastructures. See the reasons why.





**Take Control of Serialized Operations with Serialized Product Intelligence** 

Learn how TraceLink can help you boost the efficiency of serialized operations. **View More** 





#### Case Study: IBSA | Using Serialization to Ensure Product Integrity

Learn how IBSA used serialization to protect their product from counterfeiting.





Case Study: Ferrer | Building a Master Data Strategy for EU FMD

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CMO Line Upgrades: Who Will Pay?

Pharma companies and CMOs must work together closely to be ready for serialization, yet there is no established commercial model. Learn about the dynamics.