RESOURCES

Four Reasons Why Pharma Companies Need a Serialization Intelligence Solution



Your serialization processes are finally up and running, potentially across multiple global markets and many physical sites, and they're generating anywhere from a million to 100 million serialized events every week. The next step is to use that data to help ensure products are moving seamlessly along the supply chain.

What's the best way to reconcile your serialization operations among multiple systems, and ensure your operations comply with GxP requirements? How can you acquire near real-time visibility into serialization operations, and track people and systems that perform operations across your serialized infrastructure? How can you quickly access actionable insights and discover opportunities for operational improvements?

The right serialized product intelligence solution can do all these things and a great deal more. Here's a closer look at four leading reasons why today's pharmaceutical companies require a powerful serialization intelligence solution.

1. Serialization process exceptions can be expensive

With serialization comes process exceptions that can result in costly shipment delays, prolonged investigations, and even drug shortages.

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A serialization process exception occurs when there is a mismatch between compliance data representing the expected state of serialized product as it travels through the manufacturing or distribution process, and the actual state of physical product during that process. For example, a process exception could be generated during shipping when there is a discrepancy between what is expected and what is delivered.

Exceptions can be caused by serious problems, such as products being intercepted during shipment. But oftentimes, they're the result of simple data errors. Whatever the reason, exceptions can cause lengthy delays as teams comb through systems to determine the root cause of the issue and work to achieve compliance again. Some problems that can result from serialization process exceptions include:

- Product delays, resulting in drug shortages that impact patients and give competitors with rival products an advantage
- Financial loss due to product expiry or obsolescence, which can have a substantial impact on smaller manufacturers with fewer products
- Operational inefficiency, as business operations come to a halt while teams investigate and redeploy resources to remedy the issue
- Diminished or lost trust between trade partners that results from a failure to meet expectations or service levels
- Government fines, stemming from incidences of noncompliance

With the right serialized product intelligence solution, pharmaceutical companies can quickly investigate and identify the root causes of exceptions, determine if they are the result of false positives or serious problems, and resolve them quickly to keep products moving through the supply chain.

2. Manual reporting is complicated and error-prone

Companies that opt to manage serialization data reporting in-house face major obstacles, including risks associated with mistakes, complexity, and high costs.

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A typical process for creating reports for audits or exception handling can take many days or weeks depending on the scope of the problem being investigated, the amount of data being reconciled, and the number of employees available to work on the project.

To manually create reports, employees first need to download serialization data from multiple sources. The next step is combining this information into aggregate data files. Employees then need to spend a great deal of time manually reconciling the aggregated data. They also need to look for errors and omissions, which may be all but impossible to find manually considering that there could be millions of rows of serialization data to be processed.

A serialized product intelligence solution provides end-to-end visibility into serialization processes and offers automated reporting, saving pharmaceutical companies the time, risk, and expense of creating reports in-house.

3. Serialization intelligence enables companies to demonstrate compliance with ease

Pharmaceutical companies produce massive amounts of data in their serialized processes and face GxP requirements to maintain auditable governance controls.

One of the biggest pain points pharmaceutical companies face when troubleshooting errors for traceability or demonstrating GxP compliance is discovering “who did what, and when they did it.” A serialization intelligence solution that enables flexible querying of audit log data, which covers actions from all serialization-related applications, is an excellent starting point for tracing products, users, and actions across the serialization infrastructure.

Serialized product intelligence also enables users to search for and retrieve events based on a batch or batches of serial numbers. For example, suppose a European Union inspector asks for proof of systematic compliance with the EU's Falsified Medicines Directive. Users can access the full event history of every serial number

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in a batch and use this information as proof of compliance.

Additionally, serialization intelligence enables serial number reconciliation. With serial number reconciliation capabilities, users can:

- Search and retrieve summary statuses for all commissioned serial numbers.
- Gain quick access to the last compliance action recorded on all serial numbers.
- Verify that generated compliance submissions are correct for underlying business operations.
- Verify all serial numbers are compliant, thereby catching errors or omissions.
- Identify products that may have unreadable or otherwise damaged barcodes, a process that is particularly important for saleable returns.

Finally, serialization intelligence enables rapid commissioned-lot reconciliation and transaction analysis. With commissioned-lot reconciliation, users can find every lot produced for any product and access a summary of how the lot was aggregated and the lot's current disposition. With transaction analysis, users can get a comprehensive analysis of data exchanges with both internal and external partners.

4. Serialization intelligence rapidly provides answers to urgent questions

Suspect product investigations, serialization process exceptions, audits, and compliance reports demand quick answers to important questions. Some examples of the types of questions companies can answer with a serialized product intelligence solution include:

- What is every serial number associated with a specific batch?
- Has every serial number in a batch been communicated to the appropriate government authority?
- What is every event that occurred against every serial number for product X,

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lot Y, at location?

- How many messages exchanged with trading partners failed within the last two months?
- What is the quantity of product that has been produced for Product X, Lot Y, at Location Z?

Achieve end-to-end visibility with TraceLink

With its more than 274,000-member network and proven track and trace solutions, TraceLink is uniquely positioned to provide customers with automated reporting and end-to-end visibility into serialized products. With Serialized Product Intelligence from TraceLink, customers can expect to benefit from:

- A single source of truth for all serialization users
- An automated solution with no work required to download and reconcile serialization data
- A powerful and sophisticated data model that understands the business context behind serialization
- An intuitive and highly interactive user interface
- A high-performance and scalable cloud environment that is always on

Additionally, the power of the TraceLink network enables companies to benchmark key data, take advantage of shared knowledge through collaborative information sharing, and gain visibility into known exceptions or challenges within given markets.

With TraceLink, customers can spend less time dealing with serialization process exceptions and more time focusing on patient care and the bottom line. Contact TraceLink to learn more about Serialized Product Intelligence today.

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

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