



Take Action and Take Control: The Case for Serialized Product Intelligence

Leveraging the Value of Serialization Data for
Track & Trace Business Operations



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Leveraging serialization data to activate 5 key drivers of business value

Since its introduction in late 2019, Serialized Product Intelligence has become one of TraceLink’s most highly anticipated new solutions as companies continue to become aware of its potential to unlock the value of their fast-growing serialization data repositories. As they talk with manufacturers, TraceLink product managers and solution consultants have gathered a new understanding of how companies of different sizes, in diverse categories, and representing varying business models define business value. To them, the ability to leverage serialization data opens new opportunities to:



Reduce the cost of delays and risks of non-compliance



Monitor and manage trading partner activity to ensure medicine availability



Empower Track & Trace teams to drive cost efficiencies and operational excellence



Drive operational scalability and business continuity



Unlock the value of serialization data for functions across the enterprise

Can a single application meet the needs of a broad range of business goals and objectives? Yes. Serialized Product Intelligence is a powerful “multi-purpose tool” that allows pharma companies and contract manufacturers of all sizes and business models to leverage the value of their serialization data to solve *their* unique challenges and unlock new opportunities for operational efficiency and business growth.



SERIALIZATION: A common denominator linking a global supply chain

With more than 50 markets expected to implement track and trace mandates by 2025, serialization has permanently altered the pharmaceutical industry and is driving the digital transformation of its global supply chain. Whether your company manufactures branded, generic, or specialized medicines; does business in a single market or multiple markets; manufactures one or two products or hundreds of SKUs; maintains its own manufacturing and packaging sites or operates as a virtual company, serialization is a common language that can be analyzed—and leveraged—to streamline supply chain operations and create new business opportunities.

The growing role of serialized operations in business planning

Regardless of their size or operational complexity, manufacturers must implement serialization and reporting solutions to meet an expanding number of track and trace mandates in major markets around the world. Serialization is now an established component of business operations and supply chain management. As a result, companies are sitting on a large and growing source of data that can be leveraged to address a range of business opportunities that go beyond managing exceptions and resolving serialization issues.



Business Opportunity	Business Reporting	Cost Avoidance	Risk Avoidance	Business Growth	Operational Efficiency	Issue Resolution	Leveraging Data
Operational Complexity	< \$100MM Annual Sales		\$100MM to \$1B Annual Sales		> \$1B Annual Sales		
	<ul style="list-style-type: none"> • 1 – 2 Products • 1 – 2 CMOs • 1 – 2 Regulated Markets 		<ul style="list-style-type: none"> • 1 – 15 Products • 10+ CMOs / 1 - 5 3PLs • 1 – 3 Regulated Markets 		<ul style="list-style-type: none"> • 100+ Products • 50+ CMOs / Many 3PLs • 3+ Regulated Markets 		
	0–4 per year		3–4 per month		3–4 per week		
Serialization Issues	0–4 per year		3–4 per month		3–4 per week		

As companies grow in size and operational complexity, the opportunities for leveraging serialized data intelligence to pursue new business goals also grow accordingly. More important, serialized operations have the potential to become an *enabler* of growth rather than a barrier to entering new regulated markets.

Serialized operations: 4 critical business challenges

As manufacturers assess the state of their serialized operations and prepare to meet new mandates in new markets, they face a number of challenges that threaten to disrupt their business operations or prevent them from meeting their business objectives. These issues fall into four primary areas:



REACTIVE ISSUE MANAGEMENT. Across the board, companies of all sizes cite the need for more proactive monitoring of serialization operations to spot potential issues and exceptions early enough to take corrective action and respond more quickly to inquiries and investigations.



LACK OF VISIBILITY INTO THE SERIALIZED SUPPLY CHAIN. While lack of visibility into serialized events is a concern shared by a wide range of companies, their reasons differ. Many simply want a better way to monitor their contract manufacturers and benchmark their performance. However, for companies with greater operational complexity and a large number of contract partners, lack of visibility can result in a lack of control and the potential for compliance issues and product delays. Greater visibility is also seen as a way to generate insights into operations, make data-driven decisions, and drive operational excellence.



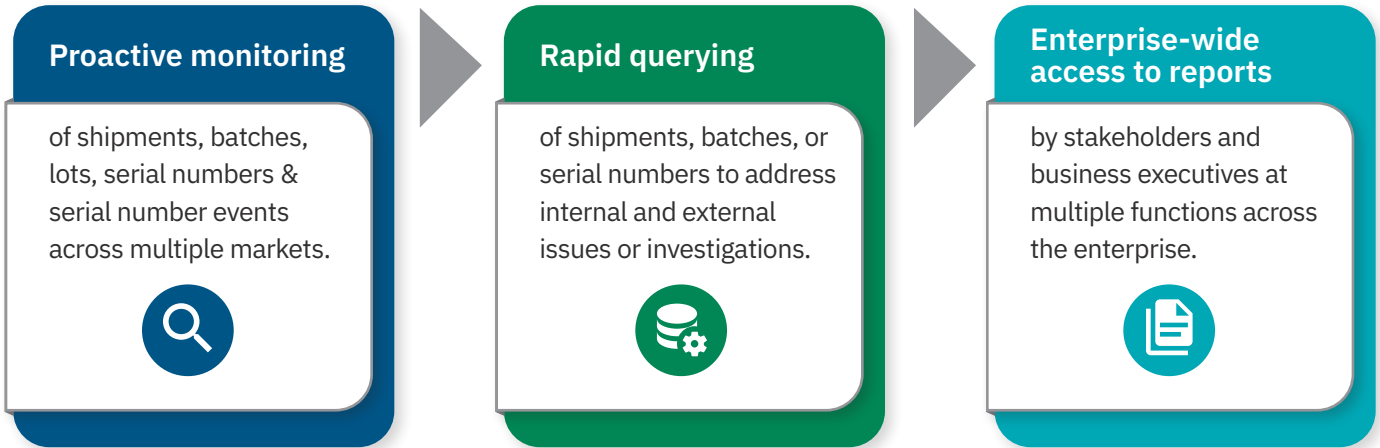
INEFFICIENT MANUAL PROCESSES. For many mid-size and large companies, extracting and analyzing serialization data remains a highly manual, spreadsheet and XML file-based process used almost exclusively for forensic investigations into serialization exceptions and compliance issues. As a result, exception management often requires long hours or days spent by large teams of full-time employees (FTEs) to identify and resolve issues. Manual tools and processes also prevent companies from taking advantage of serialization data to improve operational efficiency and business outcomes.



LIMITED RESOURCES AND BUDGET. Small to mid-sized companies without sophisticated ERP and analytics systems are especially constrained by the lack of dedicated resources to track serialized inventory and respond to questions, inquiries, and investigations raised by both internal and external parties. Opportunities for growth and expansion may also be limited by the lack of budget to hire and train additional FTEs.

Eliminating the serialization “black box”

Serialization data represents millions of discrete events and points in time in the pharmaceutical supply chain and, without a way to search, sort, and filter these events to find the proverbial “needle in a haystack,” serialization will continue to be a “black box” of untapped potential. Serialized Product Intelligence (SPI) provides an intuitive “presentation layer” for turning this data into useful, actionable information:



Serialized Product Intelligence enables faster exception management and issue resolution. It provides a multidimensional view of your serialized inventory—a “single source of truth” for tracking products across internal and external sites as well as multiple regulatory markets. For hybrid and virtual companies, SPI provides critical visibility into their network of contract manufacturing and packaging partners and a common reference point for troubleshooting issues and benchmarking supplier performance.

Rapid Querying with Serialized Product Intelligence (SPI)

The screenshot displays the 'Advanced Search' interface of SPI. It features a list of search criteria on the left and their corresponding values on the right. A 'SUBMIT' button is visible at the bottom of the search form.

Search Criteria	Value
Lot Number	0-10-06
Internal Material Number	
Packaging Code	
Packaging Code Type	0-11-05
Packaging UOM	
Product Release Date	
Product Released	d med
Product Description	
Target Markets	
Initial Commission Date	
Initial Commission Quantity	
Initial Commission Location ID	
Initial Commission Location Name	
Manufacturing Date	06593037682
Expiration Date	06593037682
Country Drug Code Type	06593037682
Country Drug Code	06593037682
Aggregated	06593037682
Dosage	06593037682
Strength	06593037682
Package Size	06593037682

SPI lets compliance, serialization, and supply chain teams use intuitive search and filter tools to surface critical information, replacing manual scanning of endless XML files and event logs.

Leveraging serialization data to achieve business objectives

With increased visibility into serialized product inventory, companies can transform serialized operations into a center of operational excellence that is central to business success in regulated markets:

Revenue Continuity

- Ensure product availability by tracking serialized inventory produced and shipped by market.
- Identify potential sales delays and avoid losses due to compliance issues that block product shipments and impact service levels.
- Avoid inventory scrap, expiry, and returns due to compliance issues, particularly for high-value inventory.

Cost Control

- Reduce the cost of unexpected compliance issues through increased visibility and proactive monitoring.
- Empower existing FTEs to manage serialization programs more efficiently.
- Avoid the cost of hiring additional FTEs to perform manual data analysis as serialized operations are scaled to meet new markets and mandates.

Risk Avoidance

- Take proactive steps to avoid compliance issues that may impact revenue and brand/product reputation.
- Respond quickly to regulatory inquiries, audits, or inspections to prevent compliance infractions and possible penalties.
- Ensure accurate, thorough, and rapid product recall processes.

Resource Management

- Free up capacity of key resources to focus on strategic business initiatives rather than forensic analysis, exception management, and issue resolution.
- Ensure business continuity using SaaS-based tools and standard operating procedures in place of ad-hoc processes and complex spreadsheets.
- Eliminate “single point of failure” and reliance on individual knowledge and skill sets.

A Multi-Dimensional View of Serialized Operations

Serialized Product Intelligence provides multiple ways to review, reconcile, and analyze the status of your serialized product inventory.

SPI in action: Russia compliance

Compliance is still a key business concern, especially in countries with complex regulatory requirements and reporting workflows that can stop or delay delivery at multiple points in the supply chain. With more than three dozen reportable events that span the product journey, no market has more complex regulatory requirements than Russia. Serialized Product Intelligence provides advanced functionality and multiple views into serialized operations that allows companies to look at the full range of Russia reporting events to identify potential issues that may delay product delivery or trigger additional reporting exceptions:

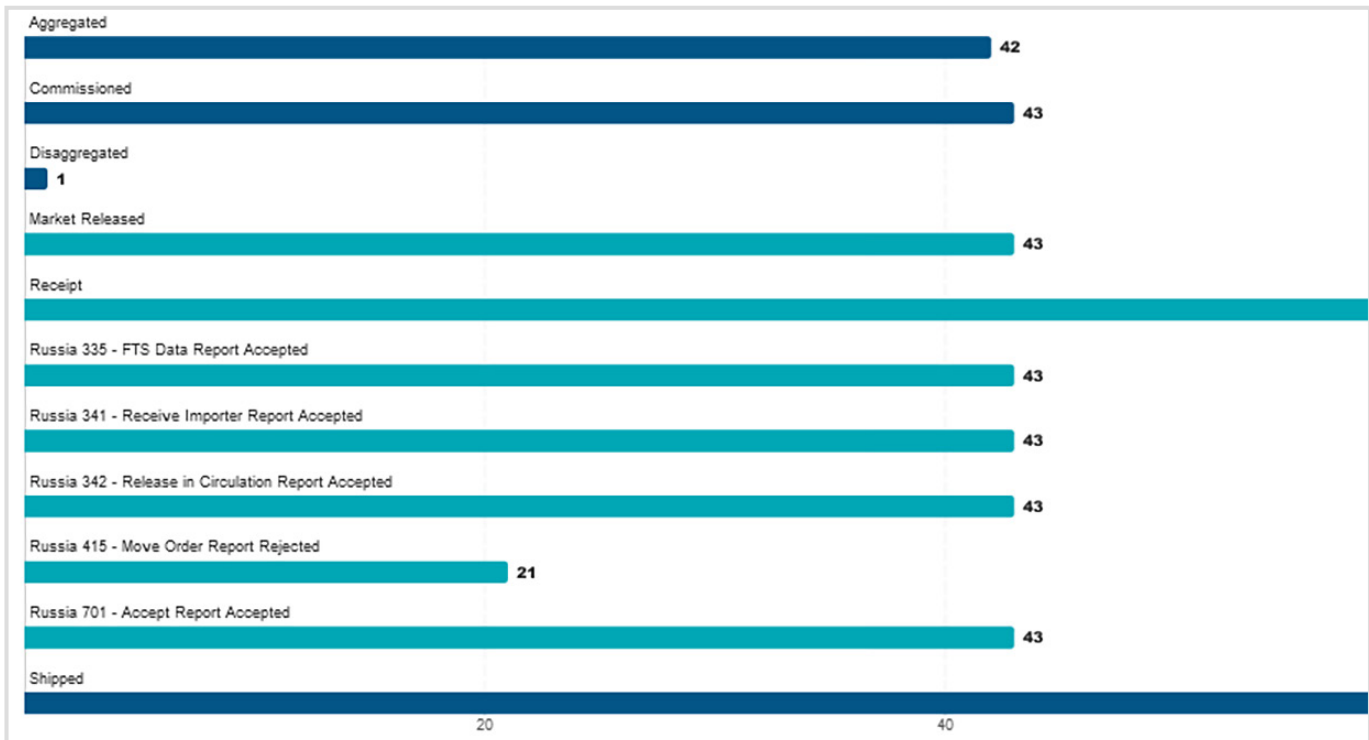
View Serial Number Event Data

Narrow the data in the table by entering a keyword or adding filters.

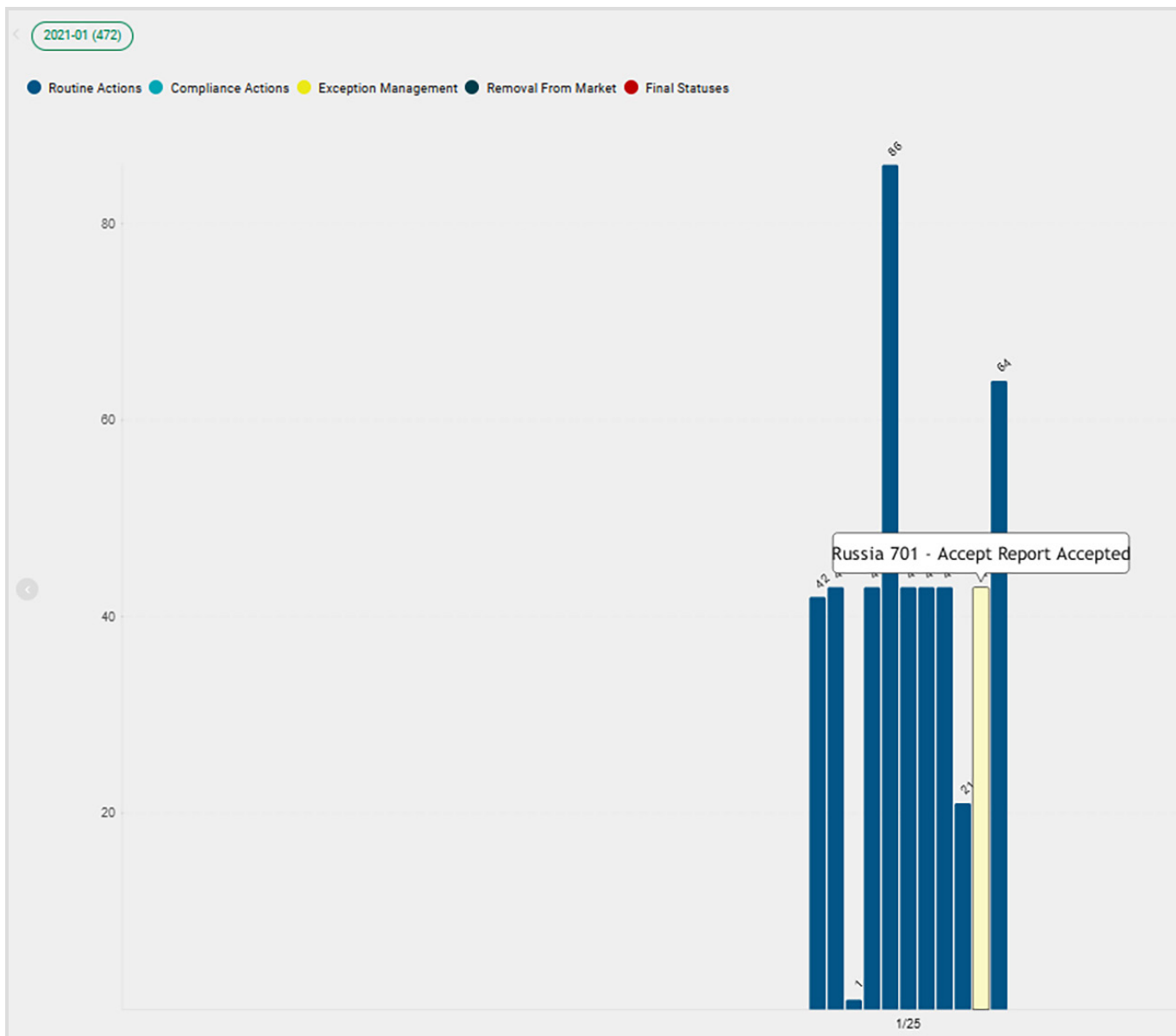
ADD FILTERS

	Event Date	Serial Number ▲	Operation	Serial Number Status	Item Status
>	2021-01-25 19:08:58.540	00138888130000003968	Commissioned	Commissioned	PendingReceipt
>	2021-01-25 19:22:04.876	00138888130000003968	Aggregated	--	--
>	2021-01-25 20:38:21.839	00138888130000003968	Russia 701 - Accept Report Accepted	--	--
>	2021-01-25 20:38:21.839	00138888130000003968	Receipt	Commissioned	PendingReceipt
>	2021-01-25 20:51:33.765	00138888130000003968	Russia 335 - FTS Data Report Accepted	--	--
>	2021-01-25 21:30:30.446	00138888130000003968	Shipped	Commissioned	PendingReceipt
>	2021-01-25 21:37:19.901	00138888130000003968	Receipt	Commissioned	PendingReceipt
>	2021-01-25 21:37:19.901	00138888130000003968	Russia 341 - Receive Importer Report Accepted	--	--

Complex reporting data can be quickly rendered to provide visual reports for compliance, serialization, and supply chain teams.



Data sets are categorized and color-coded to identify critical actions and resolutions.



Business rules and regulatory requirements are factored into the status reports.

End-to-end visibility in as little as 30 days

Serialized Product Intelligence lets companies plan and implement their global compliance strategies quickly and confidently—without extensive system integration and partner onboarding requirements. SPI’s out-of-the-box capabilities are designed to give you and your network of trading partners immediate access to near real-time data—and deliver measurable ROI within 30 to 45 days of implementation for companies of all sizes and at all levels of operational complexity—without costly, time-consuming configuration, deployment, or ongoing support.



CONTRACT MANUFACTURING: Improving customer service and retention

Serialized Product Intelligence (SPI) helps marketing authorization holders (MAHs) work more closely with their contract manufacturing partners—and vice versa. For CMOs (contract manufacturing organizations), SPI provides immediate visibility into the status of shipments of serialized products and inventory held at plants, warehouses, and third-party logistics partners (3PLs).

With SPI, CMOs can:



Improve customer service. CMOs can quickly reconcile issues when customers receive alerts or find discrepancies and respond to customer inquiries and investigations on any product, lot, serial number or shipment in any market. SPI also lets CMOs proactively identify the cause of failed messages before products arrive at a 3PL.



Invoice on time and reduce costs: CMOs can invoice customers on time by avoiding shipping delays due to serialization issues and reduce the costs of carrying excess inventory and expedited shipping to meet delivery commitments.



Meet service, compliance, and quality levels. SPI lets CMOs monitor commissioned batch releases and quality releases to flag potential discrepancies; track product storage and transportation status; and avoid sales delays due to compliance errors.



Free up resources. SPI frees up customer service teams to focus on generating new business and on-boarding new MAH accounts by automating manual processes and providing access to serialized product data without IT assistance.



Leverage your serialization investment with TraceLink

As you grow your business and enter new markets, your wealth of serialization data will only grow larger and more valuable. Serialization data created on the TraceLink network is the only time-sequenced, granular data that enables quick and proactive issue identification and resolution. Serialized Product Intelligence gives you immediate visibility to near real-time data shared among your network of trading partners and provides proactive, continuous monitoring of events and disruptions to help you capture exceptions early and initiate fast corrective action to resolve them quickly.

SPI provides out-of-the-box capabilities and requires no IT resources for implementation. At the same time, SPI lets IT teams download clean, curated data to feed into internal business systems. SPI is designed to deliver measurable ROI within 30 to 45 days of implementation for companies of all sizes and at all levels of operational complexity.

Contact TraceLink to learn more about Serialized Product Intelligence and to request a product demo.

