

Serialized Product Intelligence

Achieve Operational Excellence in Russia
with Proactive Supply Chain Monitoring



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NETWORK FOR GREATER GOOD

Serialized Product Intelligence

Your Competitive Advantage in Russia



Turn the World's Most Challenging Regulatory Landscape into a Business Opportunity

For companies facing the challenge of meeting Russia's complex serialization and reporting requirements, achieving continuous compliance while maintaining the uninterrupted flow of products requires unprecedented visibility into serialized operations. The need for precise coordination to track product movements at every step in the Russia supply chain—and the need to quickly pinpoint and resolve irregularities before they affect product availability—calls for a new breed of data-driven analytical tools that go beyond manual processes and color-coded Excel™ files.

Serialized Product Intelligence™ from TraceLink can help companies leverage serialization data to streamline serialized operations in Russia, achieve end-to-end visibility across their operations, and drive operational excellence across their business. Serialized Product Intelligence provides multifaceted visibility into product disposition at every level—from individual unit to aggregated pallet—and at any point in the journey of a serialized product.

With Serialized Product Intelligence, companies can use actionable insights to prevent delays, mitigate risk to revenue, and improve the agility of their Russia supply chain.

Take Control of Complex, Evolving Reporting and Choreography

The scope of Russia regulations significantly exceeds that of any other country's compliance standard, with a daunting array of reporting events and business and government system notifications. Even as these requirements are evolving, the government remains firm on deadlines and enforceability. In response, many companies are adding resources and ramping up the effort to ensure accurate reporting, track message delivery and receipt, and maintain audit trails to minimize the risks of non-compliance and communication failures.

WHAT ARE YOUR PEERS SAYING?

“ I know every company serializing in Russia will face the problem of managing production quantities. How do you make sure that you serialize and ship exactly the right amount of products that you are reporting to the Russian regulatory system? ”

Pasi Kemppainen

Head of Global Supply Chain
Traceability & Digital Strategy,
Santen Pharmaceutical

Russian regulations span an array of regional and governmental organizations, systems, and processes. Companies must:

- Serialize all pharmaceutical products distributed in Russia
- Report every step they make in the supply chain, and
- Capture financial data along the way.

In addition, companies must report their circulation in the market to MDLP, Russia’s centralized national track and trace system. MDLP was established to trace pharmaceutical products from their source to the end consumer. System governance is managed by a public-private partnership: the Russia Federal Tax Service controls it and the Advanced Technology Development Center, or CRPT, operates the system.

Russia Reporting Requirements Vary Based on Use Case

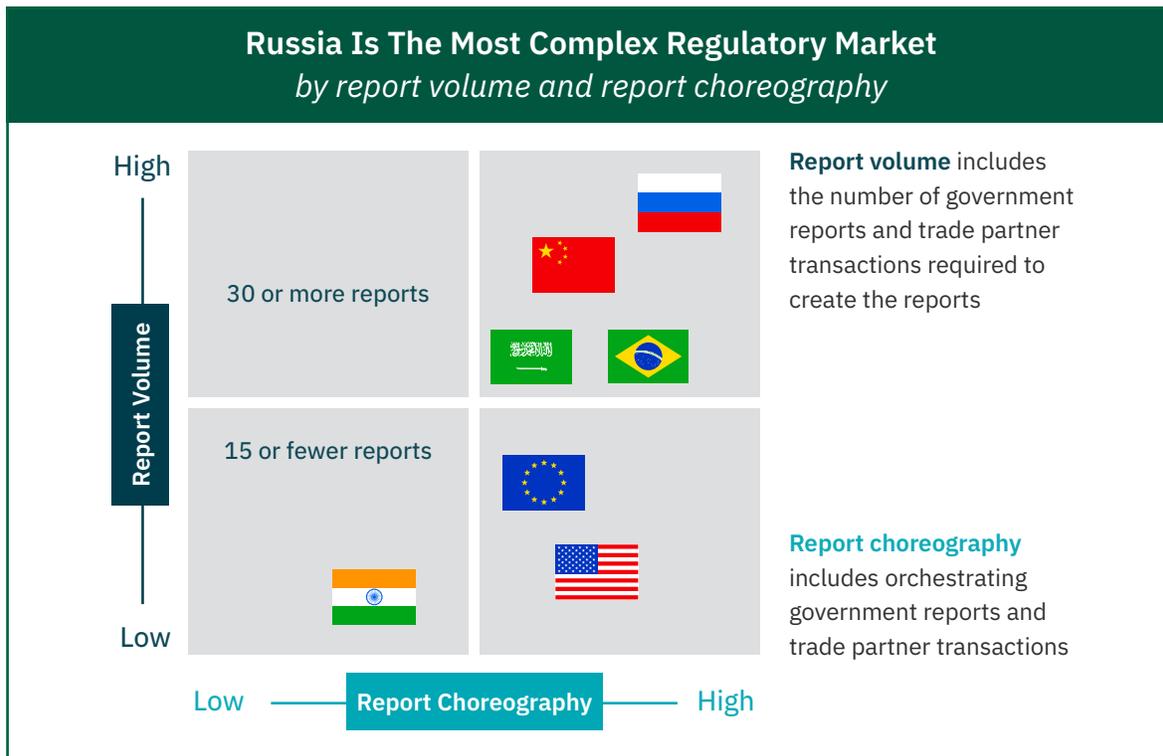
Where and how companies package their products matters. MDLP regulations cover various stages of the pharmaceutical product lifecycle depending on the use case for each Marketing Authorization Holder (MAH), including:

- Manufacturer importing aggregated product
- Manufacturer importing non-aggregated product
- Foreign manufacturer using CMOs in Russia
- Manufacturer operating within Russia
- Manufacturer acting as distributor for others

Each Use Case May Comprise Dozens of Reportable Events

Compared to reporting requirements for products distributed in the EU under the Falsified Medicines Directive (FMD), the sheer number of reporting events in Russia—as well as business and government system notifications—presents a significant challenge to efficient serialized operations and rapid exception management. Based on the latest MDLP schema, manufacturers are responsible for potentially dozens of reporting events for each use case—plus reconciliation against downstream receipt activity reports from trade partners.





Russia continues to be the world's most complex regulatory mandate.

Complex Event Choreography Requires Precise Business Logic

The high volume of reportable events requires highly detailed business logic to trigger reports and notifications based on a wide array of business conditions. Companies will receive various notifications from the centralized national track and trace system, including order acceptance or rejection, and must provide a set of core communications capabilities:

- Send digitally signed messages to central system
- Receive and process message receipts
- Sequence messages
- Archive sent and received messages
- Maintain audit trail of actions from messages

In addition, companies need a systematic approach to capturing all notifications to inform operational decisions and to maintain a proper audit trail.

Changing Russia Regulations Require a Flexible SaaS Approach

Based on the significant number of revisions since Russia's Federal Law No. 425-FZ was first published in 2017, companies should expect that Russian requirements will continue to evolve. For example, the operation of the government system is now under the control of CRPT and the cryptographic additions to the serial number have been clarified only recently. Companies are up against a moving target—yet the government remains firm on enforcement.

Given the scope and scale of the challenge in Russia, companies cannot rely on manual processes such as scanning endless XML files to identify exceptions and managing serialized operations using intricate, home-grown spreadsheets. The need for a flexible, scalable, and intuitive solution to enable enterprise-wide access to the most up-to-date serialization data is compelling.

Leverage Proactive Monitoring and Self-Service Analytics with Serialized Product Intelligence

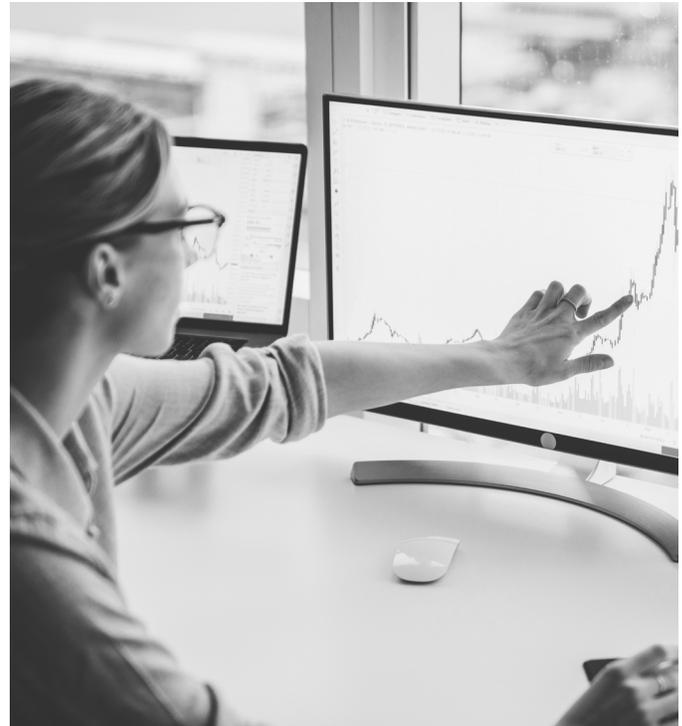
Serialized Product Intelligence (SPI) is a cloud-based application from TraceLink that provides actionable intelligence for serialized operations. With SPI, pharmaceutical companies of any size can proactively monitor the status of serialized medicines in their supply chain; accelerate exception management and resolution; and prevent costly interruptions to the delivery of products.

SPI replaces raw data, manual processes, and spreadsheets with easy-to-use dashboards and reporting tools that provide:

- Immediate visibility into commissioned serial numbers and serial number events
- Drop-down filters that let users refine results based on product, packaging level, and target market
- Pre-configured intelligence based on regulatory requirements and business rules
- Near real-time visibility into trading partner (CMO/CDMO) activity
- Automated synchronization of incoming serialization data and events
- A centralized, uniform source of insight into serialized operations across the supply chain

CORE SPI CAPABILITIES

-  Review Serial Number Events
-  Reconcile Serial Numbers
-  Monitor Commissioned Lots



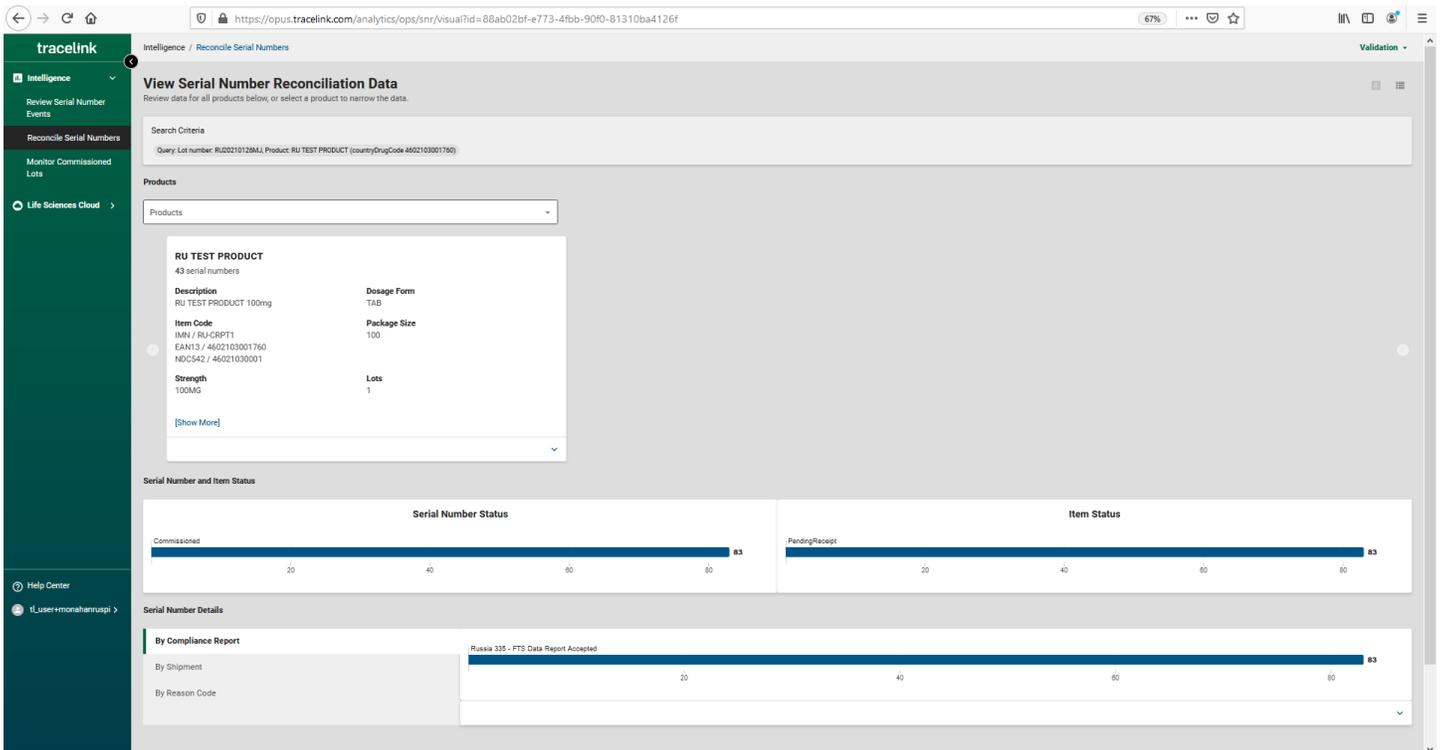
Improve Operational Efficiency while Reducing Delays and Disruptions

An important benefit of SPI is that companies can free up full-time employees (FTEs) to work on more value-added activities and avoid the cost of hiring additional FTEs while reducing the chance of human error. If your business depends on CMOs and 3PLs, SPI gives you broader visibility into trading partner activities and helps avoid having one become “a single point of failure.”

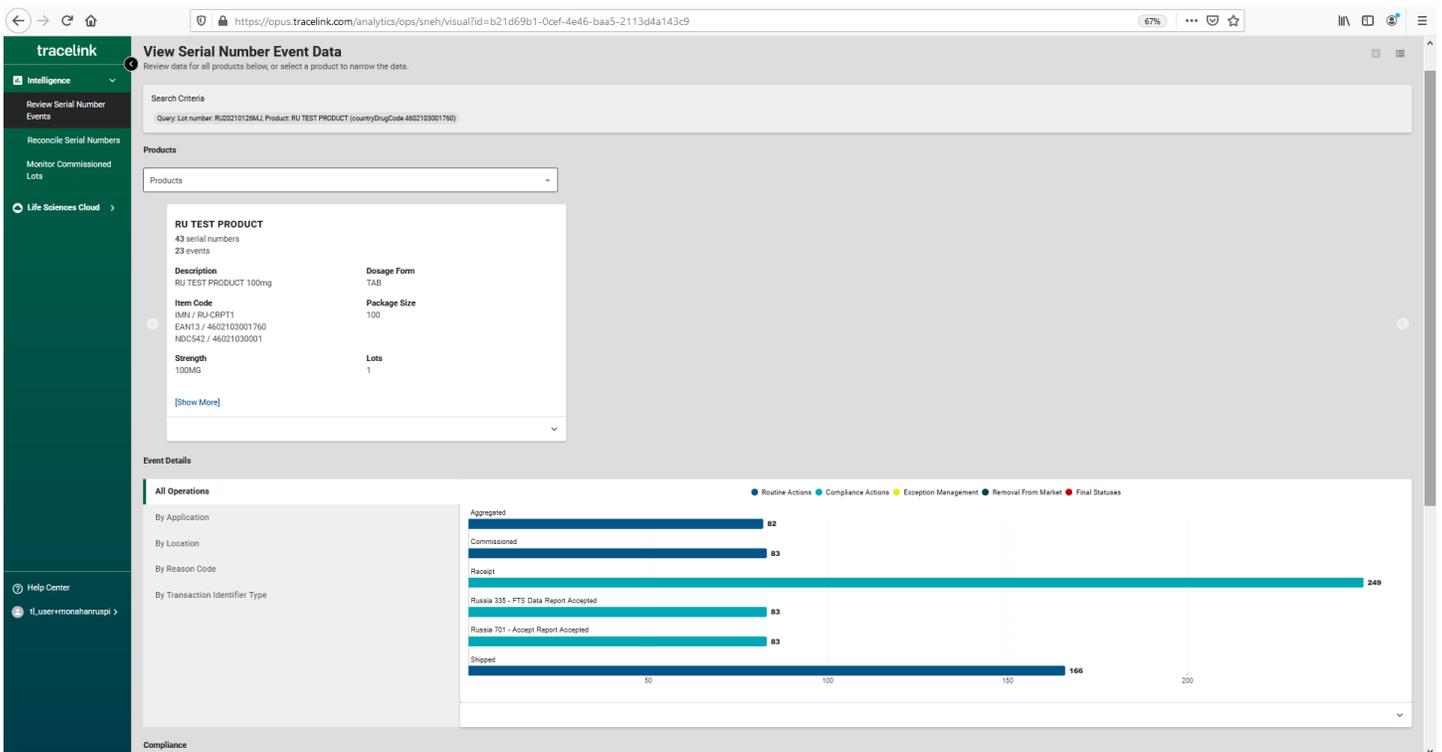
Monitor Serialized Operations to Ensure Russia Compliance

Serialized Product Intelligence (SPI) gives you greater control of your serialization operations in the Russian market. With visibility into a broad set of serialization data, you can quickly verify that your products are on track to meet demand targets. If you detect a serialization exception or reporting failure, you have the data you need to launch immediate action and prevent a potentially costly and time-consuming supply chain disruption.

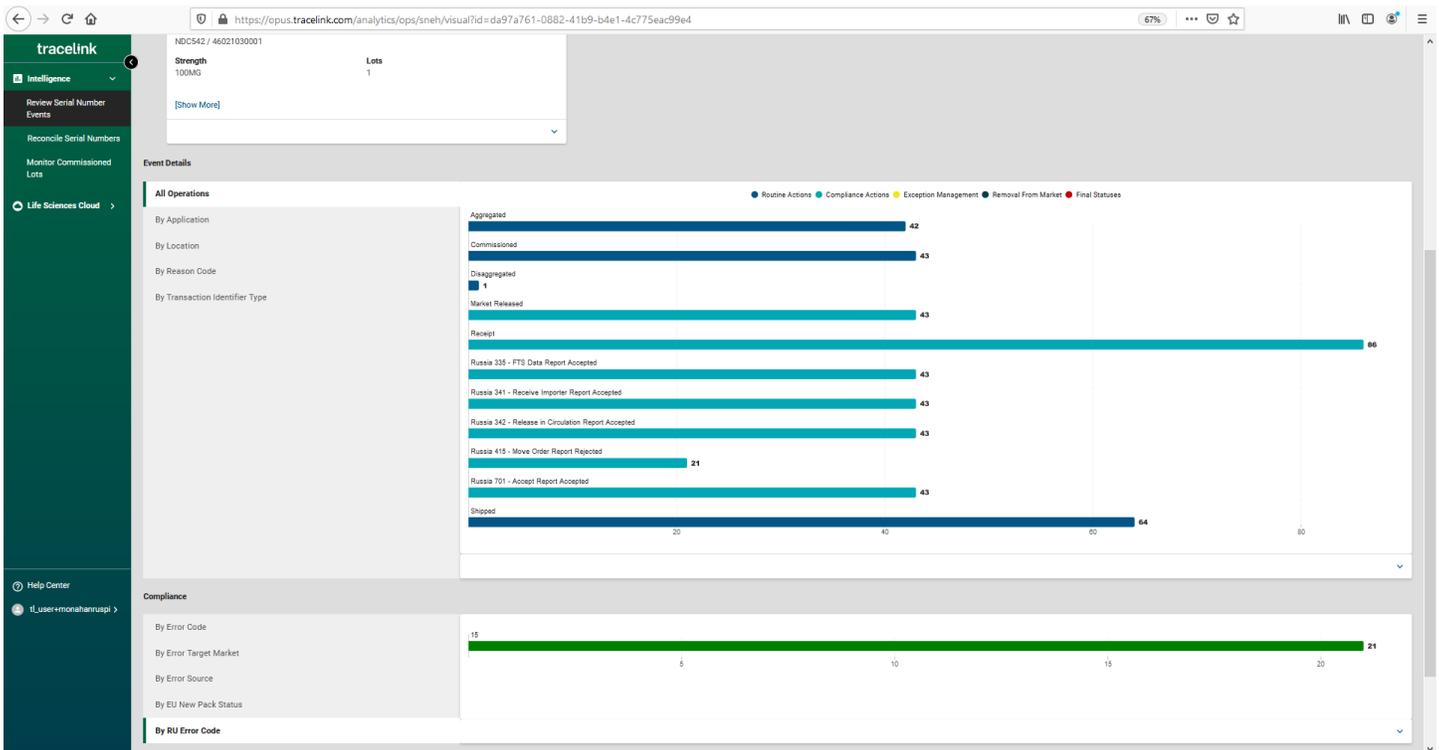
SPI lets you monitor and reconcile product quantities between compliance and operations or between shipment and delivery. Simply launch the Intelligence panel to Review Serial Number Events, Reconcile Serial Numbers, or Monitor Commissioned Lots. SPI lets you review products or events within a specific date range, narrow the data down with relevant filters, view a pre-computed status report, and then take any necessary actions based on the results.



View Serial Number Reconciliation Data for any product by Compliance Report, by Shipment, or by Reason Code



View Serial Number Event Data across All Operations, including Routine Actions, Compliance Actions, Exception Management, Removal from Market, or Final Status. Or view by event data by Application, Location, Reason Code, or Transaction Identifier Type.



View Serial Number Event Data by Russia Compliance Actions, including “ACCEPTED” and “REJECTED” reports.

View Serial Number Event Data

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

Event Date	Serial Number	Operation	Serial Number Status	Item Status	Reason Code
> 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	–	–	–
> 2021-01-25 21:53:31.366	00138888130000003968	Market Released	Commissioned	PendingReceipt	MARKET_RELEASED
> 2021-01-25 21:53:31.366	00138888130000003968	Russia 342 - Release in Circulation Report Accepted	–	–	–

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Track event history and status by individual serial number.

Gain Actionable Insights to Support and Accelerate Your Business

Establishing compliant serialization operations in Russia is a complex, business-critical initiative—and an opportunity to meet the challenging Russian mandate ahead of your competitors. Serialized Product Intelligence lets you monitor every serialized unit of sale in the market and provides the analytical tools to:

- Empower your track and trace and supply chain teams
- Shift from reactive to proactive exception management and resolution
- Scale your serialized operations quickly as your business grows

Leverage the value of your serialization data to improve supply chain performance, avoid costly disruptions, keep inventory flowing, and stay in control of your serialized operations in Russia with Serialized Product Intelligence from TraceLink. [Request a demo today.](#)

Request a Demo to Get Started with Serialized Product Intelligence

